
From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, July 2, 2020 2:30 PM
To: Coleman, Anita <Coleman.Anita@epa.gov>
Subject: Scheduling chemical meeting/briefing for aldicarb actions.

Hi Anita,

I hope you are doing well and staying safe.

Are you still in charge of RD/IO calendars and getting chemical meetings set up?

I need to put a hold on calendars (Mike G., Ed M., Catherine, Dan, and other DDs and my Aldicarb team) for early next week.

Please let me know if you do this, or if I should put out the calendar invites.

Thank you!

Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 7/6/2020 4:26:46 PM
To: Coleman, Anita [Coleman.Anita@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Scheduling chemical meeting/briefing for aldicarb actions.
Attachments: Draft Aldicarb Briefing Slides 070120 - Revised.pptx

Hi Anita,

Thank you so much for your help with the scheduling of this meeting.

We are looking for an hour time slot for the Aldicarb – New uses (Oranges/Grapefruit). The draft slides are attached. The team may be editing in the next day, but I will let you know if they need to be updated on the invite.

Thank you so much and the invitees are listed below. Let me know if you need anything else.

Debra

Invitees:

IO: Michael Goodis
Ed Messina

DDs: Marietta Echeverria (Acting RD DD)
Dan Rosenblatt
Catherine Aubee
Dana Vogel (Optional)
Kimberly Nesci (Optional)
Elissa Reaves (Optional)

The Aldicarb Team:

RD: Marion Johnson
Shanta Adeeb
Debra Rate

HED: Michael Metzger
William Donovan

EFED: Amy Blankinship
Nicolas Federoff
Stephen Wente
James Lin

BEAD: Monisha Kaul
Matthew Crowley
Mark Suarez
Rebecca Waterworth
Lindsey Hendrick
Jeana Hansel
Jonathan Becker

OGC: Alyssa Gsell
Angela Huskey
Erin Koch

PRD: Linda Arrington (Optional)
Susan Bartow (Optional)

From: Coleman, Anita <Coleman.Anita@epa.gov>
Sent: Monday, July 06, 2020 8:41 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Scheduling chemical meeting/briefing for aldicarb actions.

Good morning Debra,

I am well and safe, thank you for asking. I hope you and your family are also well and safe.

I am not sure if I can place a hold on E. Messina's calendar, I will try.

I will need the names of the DDs, Aldicarb team and length of meeting.

Thank you. Have a nice day.

Anita

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, July 2, 2020 2:30 PM
To: Coleman, Anita <Coleman.Anita@epa.gov>
Subject: Scheduling chemical meeting/briefing for aldicarb actions.

Hi Anita,

I hope you are doing well and staying safe.

Are you still in charge of RD/IO calendars and getting chemical meetings set up?

I need to put a hold on calendars (Mike G., Ed M., Catherine, Dan, and other DDs and my Aldicarb team) for early next week.

Please let me know if you do this, or if I should put out the calendar invites.

Thank you!

Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Aldicarb – Proposed New Uses

- Proposed use for oranges and grapefruit in Texas and Florida
 - Submitted April 9, 2019
- Apply granules in furrows 2 to 3 inches deep.
 - Apply only with granular applicators which use Positive Displacement Metering Units.
 - Cover or immediately deep-disk any granules spilled to ensure the granules are completely covered with at least 2 to 4 inches of soil.
- Apply granules in furrow beside individual trees and cover with at least 2 inches of soil by mechanical means.
- The maximum single application rate is 33 pounds product (4.95 lbs a.i.) per acre per year.
- Do not make more than one application per tree per year.
- Well set-back restrictions apply based on soil types.

Summary

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

Recommendations

Options: Ex. 5 Deliberative Process (DP)

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Proposed Steps Forward

- Brief upper management on risks/assessments
- Communication again with the company regarding their request for refinement of the PCTn and rebuttal claims.

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Aldicarb - Background

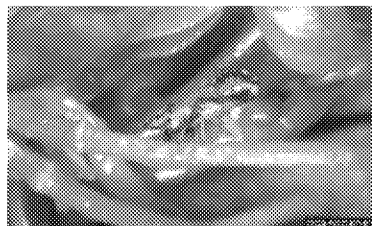
- N-methyl carbamate (NMC): to control certain insects, mites, and nematodes.
- There are no registered residential uses of aldicarb.
- Currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes.
- Restricted use pesticides due to acute oral, dermal and inhalation toxicity, and to protect ground water.

Aldicarb – Background (cont'd)

- **In 2010**, Bayer (the registrant at that time) voluntarily cancelled the domestic aldicarb uses on citrus (and potatoes), after EPA identified unacceptable dietary risk, especially to infants and young children.
 - Existing tolerances remained for citrus to allow for treated imports.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.
 - Risk estimates for dietary (food only) exposure below the level of concern (included registered domestic uses plus imported citrus commodities only).
 - Drinking water risks were mitigated by appropriate well setbacks and with in-furrow applications.
 - By restricting application of aldicarb to a depth that eliminates runoff from a treated field, the agency no longer expected exposure or risk to terrestrial and aquatic plants, or to aquatic animals.

Benefits in Citrus

- Aldicarb controls a broad spectrum of pests⁴ and has a longer period of residual activity^{1,2} than most alternatives.
- Different mode of action (carbamate; IRAC group 1A) than currently registered alternatives for psyllid control on citrus
- Low impact on natural enemies⁴, compared to currently registered alternatives³
- Based on historical usage patterns of aldicarb in citrus, growers are likely to use aldicarb for control of Asian citrus psyllid (ACP) – the insect vector of the pathogen that causes the disease citrus greening or Huanglongbing (HLB).
- Registrant claims root growth and plant health claims but lacked supporting evidence – and suggests low insecticidal benefits.



An adult Asian citrus psyllid
1/6 to 1/8 inch long
Photo by David Hall, USDA
Agricultural Research Service
Bugwood.org

¹ Qureshi et al. 2014 *PLoS ONE*; ² Childers et al. 1987 *J. Econ. Entomol.*; ³ Diepenbrock et al. 2019 IFAS Extension;

⁴ Rogers 2008 *Citrus Industry*

Huanglongbing = yellow dragon disease

Images from bugwood.org (hosted by the University Georgia) can be used as long as they are properly attributed. Only commercial uses are not allowed unless permission of the “author” is given.

Alternatives in Citrus

- Over 30 currently registered insecticides for ACP control in citrus.
 - Aldicarb, as a carbamate (IRAC group 1A), is a different mode of action compared to alternatives; carbaryl is the only registered alternative in the same group.
- For ACP control, aldicarb is less efficacious than some alternative insecticides but provides longer residual control.
- Aldicarb is likely to be quickly readopted in rotational programs in an effort to control ACP - alternative chemicals do not provide adequate control.

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Projected Percent Crop Treated (PCTn)

PCTn is the estimated percent crop treated (PCT) for a proposed new use, developed with historical usage data of market leader pesticide(s)

National analysis not appropriate

- Proposed new use is for FL and TX only
- >80% grapefruit and orange acres are in these two states
- Juice oranges grown primarily in FL

State-level PCTn for aldicarb:

Crop	State	Minimum PCTn	Maximum PCTn
Grapefruit	FL	85%	90%
Grapefruit	TX	90%	100%
Oranges (and Juice)	FL	90%	90%

AgLogic Comments and EPA Responses

- *PCTn estimates should be based on “the most current and reliable statistics, such as those provided by the USDA National Agricultural Statistics Service (NASS)”*
 - Derived from usage data available from Kynetec (Best Available Data)
 - Annual survey
 - Pest-specific data
 - Data for last 5 years of previous registration available (2007-2011)
- *PCTn should be analyzed using Florida and Texas citrus production data;*
 - Developed using state-level data
 - Interpret as percentage of crop acres grown in FL and TX that may be treated with aldicarb should the proposed new use be approved
- *Imported juice concentrate does not contain aldicarb*
 - EPA assumed 100% of imported product was treated when calculating orange PCTn
- *An appropriate PCTn for of all US orange and grapefruit acreage is 14.6%*
 - Registrant-proposed PCTn calculated using national crop production data

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Aldicarb Human Health Risks

- A highly refined acute dietary (food only) exposure assessment was conducted.
- Food only risk (Orange Juice is the risk driver):

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Aldicarb Human Health Risks (cont'd)

- Food only using drinking water level of comparison (DWLOC) approach :
 - Thus, a DWLOC level is determined by including water concentrations with food residues sufficient to give a risk level of approximately 100% aPAD for the most highly exposed population subgroup.

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Aldicarb Ecological Risks

Based on previous risk assessments

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Birds and Mammals:

- Primary risk is for birds and mammals consuming granules (1 granule can cause mortality).
 - Numerous incidents involving mortality from accidental or misuse of aldicarb. Modeling with 99.9% incorporation of granules produced RQs that exceeded the LOCs for small and medium birds and mammals.

Aquatic Organisms:

- Most aquatic organism acute and all chronic RQs exceeded all LOCs for all registered labeled uses of aldicarb.

Terrestrial Organisms:

- Highly acutely toxic to honey bees on a contact basis.
 - Although aldicarb has only granule applications which limits contact with bees, it is a systemic pesticide and

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Ex. 5 Deliberative Process (DP)

Drinking Water - Surface Water

FLcitrusSTD scenario file was used to model the citrus use. Considering the different soil incorporation depths, the 1-day average EDWCs are presented below:

Soil Depth	1-day average EDWC (ppb)	DWLOC (0.87 ppb) as percent of 1-day average EDWC	EDWC as multiple of DWLOC (0.87 ppb)
2 inches	39.2	2.22%	45
3 inches	17.0	5.12%	19.5
6 inches	4.24	20.52%	4.9

- Depending on the soil incorporation depth, the resulting EDWCs represent between 4.87 to 45 times the DWLOC (0.87 ppb).
- The citrus use label restricts use to only Florida and Texas. Since aldicarb is only registered for use on cotton and peanuts in FL and TX, the use of regional PCA was used to refine the EDWCs.

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Surface Water: Regionally Refined

The regional PCAs at HUC-2 scale for Florida and Texas on cotton, orchard and vegetables combined are shown below:

HUC-2	PCA cotton+orchard+vegetables
3 (Florida)	14.2%
12 (Texas)	20.8%
13 (Texas)	3%

The adjusted EDWCs for three regional PCA adjustments are tabulated below:

Soil Depth	1-day average EDWC (gpb)	HUC-2 3 (FL) 14.2%	HUC-2 12 (TX) 20.8%	HUC-2 13 (TX) 3%
2 inches	39.2	5.57	8.15	1.18
3 inches	17.0	2.41	3.54	0.51
6 inches	4.24	0.60	0.88	0.13

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Drinking Water - Groundwater

- GW drinking water concentrations modeled using Florida Central Ridge Scenario (co-located with citrus use) with 0.5 ft/day groundwater flow velocity.
- Additional characteristics including aldicarb's sensitivity to water pH levels and co-location with drinking water watersheds and orchards could be considered (degrades faster with increasing pH).
- For levels below the DWLOC, required well setbacks: 700 ft at pH6; 175 ft at pH7; 50 ft at pH 8.

Appointment

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 7/6/2020 1:49:39 PM
To: Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]
Subject: Quick Check-in: Aldicarb Remaining Strategy
Location: Skype Meeting
Start: 7/6/2020 3:30:00 PM
End: 7/6/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Adeeb, Shanta; Rate, Debra

Join Skype Meeting

Trouble Joining? [Try Skype Web App](#)

Join by phone

Toll number: +1 Ex. 6 Conference Code (Dial-in Number)

English (United States)

[Find a local number](#)

Conference ID Ex. 6 Conference Code

[Forgot your dial-in PIN?](#) | [Help](#)

Message

From: Waterworth, Rebecca [Waterworth.Rebecca@epa.gov]
Sent: 5/22/2020 4:21:13 PM
To: Rate, Debra [Rate.Debra@epa.gov]
CC: Hansel, Jeana [Hansel.Jeana@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Crowley, Matthew [Crowley.Matthew@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Nesci, Kimberly [Nesci.Kimberly@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: aldicarb PCTn status update and RD timeline

Hi Debra,

Thank you for the quick reply!

We do not anticipate significant changes between now and when the memo is returned from OGC. However, we are still addressing BC comments, so we are not prepared to share the draft with RD at this time. We would like to say that the current draft is not materially different than the draft of the memo that you have from the fall or even from PRP in early May.

We feel relatively confident that we can meet the seven business day deadline, which means RD will have the memo by COB on June 3. If there are any unexpected changes in our timeline, we will let you know as soon as possible.

We will confirm with our BCs and Kimberly as to whether or not we should sign the memo.

Please have a nice weekend.

Rebecca
Entomologist
U.S. Environmental Protection Agency
Office of Pesticide Programs
Biological and Economic Analysis Division
Biological Analysis Branch

Mailing address:
US EPA Headquarters
William Jefferson Clinton Building
Mail Code 7503P
1200 Pennsylvania Avenue, NW
Washington, DC 20460

phone: 703-347-8617

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Friday, May 22, 2020 9:48 AM
To: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>
Cc: Hansel, Jeana <Hansel.Jeana@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Nesci, Kimberly <Nesci.Kimberly@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: aldicarb PCTn status update and RD timeline

Hi Rebecca,

Thank you for the update on the progress of the BEAD memo.

We are thinking the next 5-7 business days would be helpful as our management is looking to raise this to higher levels. Do you believe that the memo will significantly change between now and following OGC review? If not would you be comfortable sharing a copy of the draft with RD at this time?

With respect to signatures on the memo, is there a significant benefit (or value) or downside from BEAD's perspective on whether to sign the memo or not?

Thanks.

Debra

From: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>

Sent: Thursday, May 21, 2020 2:33 PM

To: Rate, Debra <Rate.Debra@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>

Cc: Hansel, Jeana <Hansel.Jeana@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Nesci, Kimberly <Nesci.Kimberly@epa.gov>

Subject: aldicarb PCTn status update and RD timeline

Hi Debra,

The memo has passed through BC review. Lindsey, Jeana, and I will address comments over the next few business days. The memo is currently with OGC, too. We anticipate their response by mid-next week. Once BC and OGC comments have been addressed by the analysts, the document will go to Kimberly for DD review.

We would like to inquire about RD's timeline for this document. Do you have a deadline in mind?

Lastly, when we have addressed Kimberly's comments, would you like authors and BCs to sign?

Thank you,

Rebecca

Entomologist

U.S. Environmental Protection Agency

Office of Pesticide Programs

Biological and Economic Analysis Division

Biological Analysis Branch

Mailing address:

US EPA Headquarters

William Jefferson Clinton Building

Mail Code 7503P

1200 Pennsylvania Avenue, NW

Washington, DC 20460

phone: 703-347-8617

Message

From: Suarez, Mark [Suarez.Mark@epa.gov]
Sent: 7/2/2020 5:14:57 PM
To: Donovan, William [donovan.william@epa.gov]; Crowley, Matthew [Crowley.Matthew@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]
CC: Waterworth, Rebecca [Waterworth.Rebecca@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Becker, Jonathan [Becker.Jonathan@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb PCTn memo dated 29Jun2020
Attachments: Revised Proportion of Imported Oranges.pdf

Debra,

I've attached Don's 2017 update for everyone's reference.

Ex. 5 Deliberative Process (DP)

Regards,
Mark

Mark Suarez
Senior Scientist
Science Information and Analysis Branch
Biological and Economic Analysis Division
US EPA (Mail Code 7503P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

phone: 703-305-0120

From: Donovan, William <donovan.william@epa.gov>
Sent: Wednesday, July 01, 2020 8:48 AM
To: Crowley, Matthew <Crowley.Matthew@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>
Cc: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb PCTn memo dated 29Jun2020

Hi Matt,

Ex. 5 Deliberative Process (DP)

I am attaching his 2016 memo. Not quickly finding his Mar 2017 update.

Will

A.2.2. Refined Import Usage Analysis Addressing Registrant Comments.

Ex. 5 Deliberative Process (DP)

From: Crowley, Matthew <Crowley.Matthew@epa.gov>

Sent: Wednesday, July 01, 2020 6:51 AM

To: Rate, Debra <Rate.Debra@epa.gov>; Donovan, William <donovan.william@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>

Cc: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: RE: Aldicarb PCTn memo dated 29Jun2020

Interesting results, thanks Will. I would think a

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Will/HED, can you

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) ?

Matthew Crowley, Acting Branch Chief
Science Information and Analysis Branch (SIAB)
EPA/OCSPP/OPP/BEAD
703-305-7606

From: Rate, Debra <Rate.Debra@epa.gov>

Sent: Tuesday, June 30, 2020 3:17 PM

To: Donovan, William <donovan.william@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>

Cc: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: RE: Aldicarb PCTn memo dated 29Jun2020

Hi Everyone,

Thank you, Will, for running the numbers with fresh oranges at both 15% and 18% (+3% import).

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) is more appropriate?

Thanks.
Debra

From: Donovan, William <donovan.william@epa.gov>
Sent: Tuesday, June 30, 2020 11:28 AM
To: Crowley, Matthew <Crowley.Matthew@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Cc: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb PCTn memo dated 29Jun2020

Hi Matt,

Summary table attached.

Will

From: Crowley, Matthew <Crowley.Matthew@epa.gov>
Sent: Tuesday, June 30, 2020 10:39 AM
To: Donovan, William <donovan.william@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Cc: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb PCTn memo dated 29Jun2020

Interesting, thanks Will.

Can you provide a similar table of the PCTs and % aPADs results you had previously?

Matthew Crowley, Acting Branch Chief
Science Information and Analysis Branch (SIAB)
EPA/OCSPP/OPP/BEAD
703-305-7606

From: Donovan, William <donovan.william@epa.gov>
Sent: Tuesday, June 30, 2020 10:30 AM
To: Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Cc: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>;

Metzger, Michael <Metzger.Michael@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: RE: Aldicarb PCTn memo dated 29Jun2020

Hi Debra,

Ex. 5 Deliberative Process (DP)

Please let me know if you would like the full results for either run (ie all population subgroups). Thanks,

Will

From: Hendrick, Lindsey <hendrick.lindsey@epa.gov>

Sent: Monday, June 29, 2020 2:01 PM

To: Rate, Debra <Rate.Debra@epa.gov>; Donovan, William <donovan.william@epa.gov>

Cc: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: Aldicarb PCTn memo dated 29Jun2020

Hi Debra and Will,

Here is the aldicarb PCTn memo. Please let us know if you have any questions about the recommended PCTn values provided in Table 4 and summarized in the conclusion. We'll be sure to share the official, signed memo as soon as possible.

Talk soon,
Lindsey

Lindsey R F Hendrick

OPP/BEAD/SIAB

703-347-8208



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR - 1 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Revised Proportion of Imported Oranges, Orange Juice, Potatoes, and Sweet Potatoes as a Component of Total Consumption in the United States and Review of Registrant submitted Percent Crop Treated Estimate for Sweet Potatoes: Data to Support the Human Dietary Risk Assessment of Aldicarb (PC Code 098301)

FROM: Don Atwood, Ph.D., Entomologist *Donald M. Atwood*
Science Information and Analysis Branch
Biological and Economic Analysis Division (7503P)

THRU: Diann Sims, Chief *Diann Sims*
Biological Analysis Branch
Biological and Economic Analysis Division (7503P)

TO: Sue Bartow, Chemical Review Manager
Risk Management and Implementation Branch IV
Pesticide Re-Evaluation Division (7508P)

William Donovan, Chemist
Risk Assessment Branch V
Health Effects Division (7509P)

BEAD has revised the aldicarb assessment based on input from Mexico and Costa Rica. Costa Rica confirmed that aldicarb use has been banned in that country. In contrast, Mexico indicated that aldicarb is registered as a granular application for both citrus and potatoes. As such, the original document was only changed to remove Costa Rica aldicarb use in estimating percent of import dietary consumption for orange juice. The document now indicates that aldicarb acute and chronic dietary estimates for import consumption are 20% and 17%, respectively. All other estimates have remained the same as presented in the original document.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Proportion of Imported Oranges, Orange Juice, Potatoes, and Sweet Potatoes as a Component of Total Consumption in the United States and Review of Registrant submitted Percent Crop Treated Estimate for Sweet Potatoes: Data to Support the Human Dietary Risk Assessment of Aldicarb (PC Code 098301)

FROM: Don Atwood, Ph.D., Entomologist *Donald M. Atwood*
Science and Information Analysis Branch
Biological and Economic Analysis Division (7503P)

THRU: Diann Sims, Chief
Science Information and Analysis Branch
Biological and Economic Analysis Division (7503P)

TO: William Donovan, Chemist
Risk Assessment Branch V
Health Effects Division (7509P)

Sue Bartow, Chemical Review Manager
Risk Management and Implementation Branch IV
Pesticide Re-Evaluation Division (7508P)

PRP Date: September 28, 2016

This memorandum transmits the percent of imported commodity in domestic consumption for oranges, orange juice, and potatoes to support the dietary risk assessment for aldicarb which is currently undergoing registration review (Table 1). Data was adjusted to reflect only major exporter countries in which there is no indication of aldicarb ban. In the absence of a verifiable ban on aldicarb, rather than simply not registered, it is assumed that aldicarb could still be applied. Therefore, use of the percent of imports from these countries provides reasonable certainty that the estimated proportion of commodity treated will not be exceeded. BEAD also provides a review of the registrant submitted Percent Crop Treated (PCT) value for the use of aldicarb on sweet potatoes as a suitable estimate for domestic use. These data are provided in support of the dietary risk assessment for aldicarb.

Data from the Economic Research Service (ERS) and Foreign Agricultural Service (FAS) of the United States Department of Agriculture (USDA) were used to derive the percent of imported oranges, orange juice, potatoes, and sweet potatoes in domestic consumption. Percent imports as presented in this memo are defined as the quantity of imports relative to the total commodity availability, i.e., the amount of imports for the commodity (in million lbs or gal) divided by the total amount available for consumption in the US accounting for both production and exports. The average proportion of imports is calculated as the simple average of the annual percentages and is representative of the chronic PCT. The highest import consumption represents the acute PCT.

Table 1. Summary of Aldicarb Component of Selected Imported Commodities in Total U.S. Dietary Consumption.

Commodity	Recommended PCT Values	
	Average (chronic)	Maximum (acute)
Oranges	2%	3%
Orange Juice	17%	20%
Potatoes		
Fresh	0%	0%
Freezing	0%	0%
Processed	3%	4%
Sweet Potatoes	31%	34%

Oranges

The major exporters of oranges to the United States are Chile, Mexico, South Africa, and Australia (Table 2). These four countries account for 96% of U.S. orange imports. Aldicarb use has been banned in Chile, South Africa, and Australia. BEAD has verified aldicarb use in Mexico (Tovar Díaz, A. L., 2017) and as such this usage is considered in relation to domestic consumption of imported oranges in this assessment (Table 3).

Table 2. U.S. Importation of Oranges in Million Lbs from 2012-2014

	2012	2013	2014	Yearly Average
Partner	Qty	Qty	Qty	Qty
Chile	113.6	129.8	107.0	116.87
Mexico	38.4	61.6	99.7	66.5
South Africa	79.3	79.4	80.0	79.6
Australia(*)	24.5	23.0	15.0	20.8
Grand Total (world)	262.4	307.2	317.5	295.7

(*) denotes a country that is a summarization of its component countries.

Source(s): USDA/FAS 2016

Table 3. Percent Import Share in Consumption for Fresh Oranges.

Year	US Production (Million Lbs)	Commodity Export (Million Lbs)	Available domestic for Consumption (Million Lbs)	Commodity Imports (Million Lbs)	Total Available for Consumption (Million Lbs)	% Import Component of Consumption	% of Aldicarb treated Orange Imports (Mexico)*	% Imported Oranges from Mexico as Component of Total Consumption
2012	4,558.9	1,531.8	3,027.2	262.6	3,289.8	8%	14.6%	1%
2013	4,474.9	1,495.4	2,979.4	307.3	3,286.7	9%	20.0%	2%
2014	3,790.6	1,120.9	2,669.7	315.4	2,985.1	11%	31.4%	3%

Source(s): USDA/ERS 2016 and *USDA/FAS 2016

On average over the 2012 to 2014 time period, 2% of the fresh oranges with potential aldicarb usage for domestic consumption were imported. This value is appropriate for use in a chronic dietary risk assessment. A maximum of 3% of domestic consumption was imported from Mexico with potential aldicarb usage; this value would be appropriate as a measure of possible acute exposure.

Orange Juice

On average over the 2012 to 2014 time period, 73 percent of the orange juice available for domestic consumption was imported. The three largest exporters of orange juice to the U.S. are Brazil, Mexico, and Costa Rica (Table 4). These countries account for 94% of all U.S. orange juice importation. Brazil and Costa Rica have banned the use of aldicarb so there would be no contribution to aldicarb dietary consumption from this country. However, BEAD was able to determine that aldicarb is used in orange production in Mexico (Tovar Díaz, A. L., 2017) and as such is included in the assessment of domestic consumption of imported orange juice (Table 5). On average over the time period of 2012 to 2014, 17% of the fresh oranges with potential aldicarb usage for domestic consumption were imported. This value is appropriate for use in a chronic dietary risk assessment. A maximum of 20% of domestic consumption was imported; this value would be appropriate as a measure of possible acute exposure.

Table 4. U.S. Importation of Orange Juice in Million Gallons from 2012-2014.

	2012	2013	2014	Yearly Average
	Qty	Qty	Qty	Qty
Brazil	118.9	216.4	296.0	210.4
Mexico	71.8	121.8	119.6	104.4
Costa Rica	29.4	33.7	28.5	30.5
Grand Total (world)	241.4	317.1	387.5	366.7

Source(s): USDA/FAS 2016

Table 5. Percent Import Share in Consumption for Orange Juice.

Year	US Production (Million Gal)	Commodity Export (Million Gal)	Available domestic for Consumption (Million Gal)	Commodity Imports (Million Gal)	Total Available for Consumption (Million. Gal)	% Import Component of Consumption	% of Aldicarb Treated Juice Imports (Mexico)*	% Imported Juice from Mexico as Component of Total Consumption
2012	391.3	148.4	242.9	241.4	484.3	50%	29.8%	15%
2013	448.9	153.7	295.2	317.1	612.3	52%	38.4%	20%
2014	534.2	147.4	386.8	387.5	774.3	50%	30.9%	15%

Source(s): USDA/ERS 2016 and *USDA/FAS 2016

Potatoes (Total)

On average over the 2012 to 2014 time period, 14 percent of the potatoes available for domestic consumption were imported (fresh 8%, frozen 23%, and processed (chips, dehydrated, canned) 8%). Both fresh and frozen potatoes are primarily imported from Canada (Table 6). As Canada has banned the use of aldicarb, there would be no impact of aldicarb on domestic consumption.

Processed non-frozen potatoes (chips, dehydrated, and canned potatoes) are imported from Canada, Mexico, Germany, China, Italy, and the Netherlands. As aldicarb use has been banned by Canada and European Union countries, processed potato imports from these countries would not contribute to the dietary component of aldicarb in domestic consumption. Similarly, China has restricted use of aldicarb for potato production and it also would not contribute to domestic consumption. BEAD has been able to confirm use of aldicarb in Mexico (Tovar Díaz, A. L., 2017). As such, BEAD has included imported processed potatoes from Mexico as a component of domestic consumption (Table 7). Imported processed potatoes (canned, chipped, dehydrated) would contribute 3% to chronic and 4% acute dietary exposure as import component of total consumption.

Table 6. U.S. Importation of Potatoes by Type in Million Lbs 2012-2014.

Potato Product	Country	2012 Qty	2013 Qty	2014 Qty	Yearly Average Qty
Fresh	Canada	619.8	714.9	883.9	739.5
	Total (world)	619.8	714.9	884.1	739.7
Frozen	Canada	1,582.1	1,721.2	1,718.8	1,674.0
	Total (world)	1,653.9	1,755.5	1,736.5	1,716.1
Processed (non-frozen)	Canada	38.3	38.0	41.7	39.3
	Mexico	41.9	38.6	35.8	38.8
	Germany*	14.9	18.4	6.2	13.2
	China	3.0	1.9	3.5	2.8
	Italy	2.4	1.4	1.1	1.6
	Netherlands	4.6	0.1	-	1.6
	Total (world)	106.7	101.1	93.4	102.2

(*) denotes a country that is a summarization of its component countries.

Source(s): USDA/FAS 2016

Table 7. Percent of Potato Import Share in Consumption by Type (2012-14).

Potato Type	US Production (Mil. Lbs)	Commodity Export (Mil. Lbs)	Available domestic for Consumption (Mil. Lbs)	Commodity Imports (Mil. Lbs)	Total Available for Consumption (Mil. Lbs)	% Import Component of Consumption	% of Aldicarb Treated Import Potatoes**	% Import Potato from Mexico as Component of Total Consumption
Fresh (2012-2014) average	10,930.1	988.2	9,941.9	889.3	10,831.2	8%	0%	0%
Frozen (2012-2014) average	15,748.9	4,165.4	11,583.5	3,415.7	14,999.2	23%	0%	0%
Processed* (2012-2014) average	11,105.2	1,840.5	9,264.7	836.3	10,100.9	8%	38%	3%
2012	10,892.4	1,823.0	9,069.4	1,052.8	10,122.2	10%	39%	4%
2013	10,916.5	1,752.0	9,164.5	737.7	9,902.2	7%	38%	3%
2014	11,506.73	1,946.5	9,560.3	718.2	10,278.4	7%	38%	3%

(*) includes canned, chipped, and dehydrated potatoes

** imported potatoes from Mexico for Processed potatoes

Source(s): USDA/ERS 2016 and USDA/FAS 2016

Sweet Potatoes Percent Crop Treated (PCT)

BEAD also reviewed the data submitted by AgLogic Chemical LLC (August 31, 2016). AgLogic indicates that usage on sweet potatoes is restricted to the states of Louisiana and Mississippi. Based on total US sweet potato production (169,000 acres) and sweet potato production in Louisiana and Mississippi (35,000 acres), AgLogic estimated an average PCT of 21% and worst case scenario PCT of 35% (AgLogic, 2016).

BEAD reviewed national sweet potato production for the years 2002, 2007, and 2012 (USDA/NASS, 2007 and 2012) (Table 8) and confirmed the label restriction to use only in Louisiana and Mississippi. According to U.S. Census of Agriculture data, Louisiana and Mississippi sweet potato acreage ranges from 25% to 34% of total U.S. acreage (Table 8). Assuming a worst case scenario in which every sweet potato acre in Louisiana and Mississippi would be treated with aldicarb, BEAD believes a more accurate estimate for domestic dietary risk assessment based on historical sweet potato production would be 31% for chronic exposure and 34% for acute exposure.

The countries with greatest export of sweet potatoes to the U.S. include Dominican Republic, Peru, China, and Canada (Table 9). These 4 countries account for 99.1% of sweet potatoes imported by the United States. Furthermore, all 4 countries have banned the use of aldicarb. There would negligible contribution of imported aldicarb treated sweet potatoes to total consumption of sweet potatoes (Table 10).

Table 8. United States Sweet Potato Harvest for 2002, 2007, and 2012.

Year	National (acres)	Louisiana and Mississippi (acres)	Percent Crop Treated for Louisiana and Mississippi (PCT)*
2002	92,310	30,369	33%
2007	105,284	35,890	34%
2012	125,726	31,486	25%

(*) based on all harvest acres treated

Source(s): USDA/NASS 2007 and 2012

Table 9. U.S. Importation of Sweet Potatoes in Million Lbs from 2012-2014.

	2012	2013	2014	Yearly Average
Partner	Qty	Qty	Qty	Qty
Dominican Republic	14.8	14.3	15.2	14.8
Peru	8.2	9.4	12.9	10.1
China	2.5	9.0	4.5	5.3
Canada	1.2	1.0	2.7	1.6
Grand Total (world)	26.7	33.9	35.6	32.1

(*) denotes a country that is a summarization of its component countries.

Source(s): USDA/FAS 2016

Table 10. Percent Import Share in Consumption for Sweet Potatoes.

Year	US Production (Million Lbs)	Commodity Export (Million Lbs)	Available domestic for Consumption (Million Lbs)	Commodity Imports (Million Lbs)	Total Available for Consumption (Million Lbs)	% Import Component of Consumption	% of Aldicarb treated Sweet Potato Imports*	% Imported Sweet Potatoes as Component of Total Consumption
2012	2,648.2	246.3	2,401.9	26.8	2,428.7	1%	0%	0%
2013	2,478.5	280.7	2,197.8	34.1	2,231.8	2%	0%	0%
2014	2,958.4	311.1	2,647.3	36.0	2,683.3	1%	0%	0%

Source(s): USDA/ERS 2016 and *USDA/FAS 2016

References

AgLogic. 2016. Response to the US EPA Memorandum: "Aldicarb. Acute Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for Registration Review Risk Assessment," DP Barcode D430197 – Amended. Submitted document MRID 50013101 (August 31, 2016).

Tovar Díaz, A.L. 2017. Personal Communication. Subdirectora de Certificación y Reconocimiento, Dirección General De Inocuidad Agroalimentaria, Acuicola Y Pesquera.

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https://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_2_US_State_Level/st99_2_029_029.pdf

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 5/12/2020 5:41:09 PM
To: Waterworth, Rebecca [Waterworth.Rebecca@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Collantes, Margarita [Collantes.Margarita@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]
Subject: RE: aldicarb PCTn, federal register language

Hi Rebecca,

You mention that this is not the standard review. I don't think that we mind if the FR language comes out of the memo (esp. as you say since it is not appropriate for how you have done your analysis). Provided we are able to track how you accomplished your analysis and the results, I think we will have what we need from your memo.

Please also include Shanta Adeeb, PM 10 on the receipt of the memo.

Thanks.
Debra

From: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>
Sent: Monday, May 11, 2020 9:27 AM
To: Rate, Debra <Rate.Debra@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Collantes, Margarita <Collantes.Margarita@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>
Subject: aldicarb PCTn, federal register language

Hi Debra,

My teammates (copied) and I were wondering if we should include federal register language in our memo. When the document was review in PRP last week, it was included. However, the memo really isn't the standard PCTn memo anymore, especially because we include BEAD's responses to registrant claims and comments. Please know that we aren't trying to purposefully remove it. We are struggling with the document's flow or road map, as TJ Wyatt put it. As the recipients, we want to produce a document that meets your needs.

Also, there is a comment in our memo as to whether or not we should identify anyone specific in HED who should receive this memo. At the moment, we list you and Marion.

We plan to submit our memo by COB 18 May to BCs. If anything changes with our plan, we will advise you immediately.

Sincerely,

Rebecca
Entomologist
U.S. Environmental Protection Agency
Office of Pesticide Programs
Biological and Economic Analysis Division
Biological Analysis Branch

Mailing address:

US EPA Headquarters
William Jefferson Clinton Building
Mail Code 7503P
1200 Pennsylvania Avenue, NW
Washington, DC 20460

phone: 703-347-8617

Appointment

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 5/6/2020 9:21:40 PM
To: Blankinship, Amy [Blankinship.Amy@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Aldicarb - new uses
Location: Skype Meeting
Start: 5/7/2020 5:00:00 PM
End: 5/7/2020 5:30:00 PM
Show Time As: Tentative

Required Attendees: Blankinship, Amy; Johnson, Marion; Adeeb, Shanta

Hi Amy,

We would like to have a short meeting to quickly update you on our call with OGC and discuss the current drinking water modeling.

Let me know if this time does not work for you or if something comes up.

Thanks.

Debra

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English (United States)

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Appointment

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/30/2020 3:28:21 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: New Uses - Aldicarb
Location: Microsoft Teams Meeting
Start: 6/30/2020 6:00:00 PM
End: 6/30/2020 6:30:00 PM
Show Time As: Tentative

Required Attendees: Johnson, Marion; Adeeb, Shanta

Quick meeting to brainstorm next steps in light of new HED results.

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Appointment

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/11/2020 7:25:55 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Blankinship, Amy [Blankinship.Amy@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]; Donovan, William [donovan.william@epa.gov]; Costello, Kevin [Costello.Kevin@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Waterworth, Rebecca [Waterworth.Rebecca@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Becker, Jonathan [Becker.Jonathan@epa.gov]; Lin, James [lin.james@epa.gov]; Wente, Stephen [Wente.Stephen@epa.gov]; Gsell, Alyssa [Gsell.Alyssa@epa.gov]
Subject: Team Meeting - Aldicarb new uses
Location: Microsoft Teams Meeting
Start: 6/15/2020 12:30:00 PM
End: 6/15/2020 1:00:00 PM
Show Time As: Tentative

Required Attendees: Johnson, Marion; Adeeb, Shanta; Blankinship, Amy; Metzger, Michael; Donovan, William; Costello, Kevin; Suarez, Mark; Waterworth, Rebecca; Hansel, Jeana; Hendrick, Lindsey; Kaul, Monisha; Becker, Jonathan; Lin, James; Wente, Stephen; Gsell, Alyssa

Hold for discussion on Aldicarb new uses.

I have been placed on an aggressive timeline, so it is past time to check in with the whole team to quickly discuss where the action stands and next steps. I will be sending out more information by email prior to the meeting as it comes together.

I only found a free ½ hour for the team, but I am prepared to schedule a follow up meeting to continue the discussion as may be needed.

Thanks in advance for your time!!
Debra

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Message

From: Donovan, William [donovan.william@epa.gov]
Sent: 6/30/2020 3:27:53 PM
To: Crowley, Matthew [Crowley.Matthew@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]
CC: Waterworth, Rebecca [Waterworth.Rebecca@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Becker, Jonathan [Becker.Jonathan@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb PCTn memo dated 29Jun2020
Attachments: Aldicarb DEEM Results june 30 2020.docx

Hi Matt,

Summary table attached.

Will

From: Crowley, Matthew <Crowley.Matthew@epa.gov>
Sent: Tuesday, June 30, 2020 10:39 AM
To: Donovan, William <donovan.william@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Cc: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb PCTn memo dated 29Jun2020

Interesting, thanks Will.

Can you provide a similar table of the PCTs and % aPADs results you had previously?

Matthew Crowley, Acting Branch Chief
Science Information and Analysis Branch (SIAB)
EPA/OCSP/OPP/BEAD
703-305-7606

From: Donovan, William <donovan.william@epa.gov>
Sent: Tuesday, June 30, 2020 10:30 AM
To: Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Cc: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb PCTn memo dated 29Jun2020

Hi Debra,

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Please let me know if you would like the full results for either run (ie all population subgroups). Thanks,

Will

From: Hendrick, Lindsey <hendrick.lindsey@epa.gov>

Sent: Monday, June 29, 2020 2:01 PM

To: Rate, Debra <Rate.Debra@epa.gov>; Donovan, William <donovan.william@epa.gov>

Cc: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: Aldicarb PCTn memo dated 29Jun2020

Hi Debra and Will,

Here is the aldicarb PCTn memo. Please let us know if you have any questions about the recommended PCTn values provided in Table 4 and summarized in the conclusion. We'll be sure to share the official, signed memo as soon as possible.

Talk soon,
Lindsey

Lindsey R F Hendrick
OPP/BEAD/SIAB
703-347-8208

Summary of Results for Aldicarb Dietary Assessment (Food Only) Using Indicated PCT Estimates for Orange, Orange Juice, Grapefruit, and Grapefruit Juice in Support of TX, FL Section 18.

Ex. 5 Deliberative Process (DP)

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/11/2020 6:59:55 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb timeline?
Attachments: Draft Aldicarb Briefing Slides 061120 V2.pptx

Hi Marion, Shanta,

I want you both to know that I was planning to be out of the office on 6/22/20, so the planned briefing for 6/22 may need to be shifted a day in the timeline.

However, working from the timeline below, I am working to set up the meeting for the aldicarb team Monday 6/15/20. There is a half hour time slot from 8:30 – 9:00 am in which all but one person seems to be open on their calendars. Alternatively I can try to set up the meeting during lunch (which I can do but hate to....). Any thoughts?

Also attached, I've started to put together the bones of the briefing slides today. There is still a ways to go, but if you have a chance to look at it, please let me know if there are any other points that I missed in the Titles of the place holder slides. I patterned some of the slides off of the ACP briefing slides that Shanta provided (thank you!).

I hope to have the slides mostly complete by Monday morning.
Anyway, let me know what you think of the slides and the timing of the meeting?
Thanks.
Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Wednesday, June 10, 2020 12:48 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Re: Aldicarb timeline?

Debra, Shanta:

Here's the tentative timeline that I presented to Mike on Monday. It's aggressive and will, like all timelines, subject to change, but at least we're aiming for a goal.

Also, Our electricity power in our area has gone out for some unknown reason (probably construction/repair), so I'll probably have to ask the two of you to carry on with the TCVP meetings without me.

Timetable to decision (PRIA date 7/15/2020):

- ☐ 6/8/2020 IVB2 meeting with OGC's Alyssa Gsell, successor to Bob Perlis on aldicarb.
- ☐ 6/8/2020 Expected OGC comments on PCT memo to BEAD.
- ☐ 6/10/2020 HED feedback on MOEs based upon 14.6% PCT (Prod. Cap as proposed by AgLogic).
- ☐ 6/15/2020 Internal Chemical Team Meeting to consider any remaining items:
(RD/HED/EFED/BEAD/PRD)
- ☐ 6/17/2020 Finalize proposal/briefing to Senior Management to discuss findings with Registrant per OGC advice.

- ☐ 6/22/2020 Possible Briefing with Senior Management (RD and HED Director) with options, prior to contacting registrant.
- ☐ 6/24/2020 Call to Registrant to provide withdrawal, denial options.

MJJ

Marion Johnson
Branch Chief | IVB2 | RD | OPP | EPA
703 305-6788

Sent from my iPhone

On Jun 10, 2020, at 10:13 AM, Rate, Debra <Rate.Debra@epa.gov> wrote:

Hi Marion,

When you have a moment, would you be able to provide Shanta and I with a copy of your aldicarb timeline?

Thanks.
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Aldicarb - Background

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity, and to protect ground water.
- Aldicarb products are currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. There are no registered residential uses of aldicarb.
- **In 2010**, Bayer (the registrant at that time) voluntarily cancelled the domestic aldicarb uses on citrus (and potatoes), due to unacceptable dietary risk, especially to infants and young children.
 - Existing tolerances remained for citrus to allow for treated imports.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.

Aldicarb – Background (cont'd)

- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.
 - The EPA risk assessment for the 2017 ID depicted risk estimates for dietary (food only) exposure below the level of concern, which included citrus exposure from imported commodities only.
 - Drinking water risks were mitigated by appropriate well setbacks, based upon such factors such as location and soil type, and with consideration that in-furrow applications were at a depth of the one inch or greater. This analysis was inclusive for citrus in FL, even though aldicarb's domestic use on citrus had been voluntarily cancelled.
 - By restricting application of aldicarb to a depth that eliminates runoff from a treated field, the agency no longer expected exposure or risk to terrestrial and aquatic plants, or to aquatic animals.

Aldicarb – Proposed New Uses

- Proposed use for oranges and grapefruit in Texas and Florida
- Apply granules in 3 to 6 furrows that are 2 to 3 inches deep and spaced on approximately 12-inch centers.
 - Application of AGLOGIC 15GG to citrus must be made only with granular applicators which use Positive Displacement Metering Units.
 - Cover or immediately deep-disk any granules spilled during loading, at row ends, or elsewhere to ensure the granules are completely covered with at least 2 to 4 inches of soil.
- Apply granules in a furrow beside individual trees and cover with at least 2 inches of soil by mechanical means.
- The maximum single application rate is 33 pounds product (4.95 lbs a.i.) per acre per year.
- Do not make more than one application per tree per year.
- Well set-back restrictions apply based on soil types.

Aldicarb Human Health Risks

- Acutely toxic through oral, dermal and inhalation routes of exposure.
- A highly refined acute dietary (food only) exposure assessment was conducted.
- Food only risks:

Ex. 5 Deliberative Process (DP)

- DWLOC:

Ex. 5 Deliberative Process (DP)

Aldicarb Fate Profile

Aldicarb Toxicity Profile

Animals and Birds:

- Primary risk is for birds and mammals consuming granules (1 granule can cause mortality).
 - Numerous incidents involving mortality from accidental or misuse of aldicarb. Modeling with 99.9% incorporation of granules produced RQs that exceeded the LOCs for small and medium birds and mammals.
- Most aquatic organism acute and all chronic RQs exceeded all LOCs for all registered labeled uses of aldicarb.
- Highly acutely toxic to honey bees on a contact basis.
 - Although aldicarb has only granule applications which limits contact with bees, it is a systemic pesticide

Ex. 5 Deliberative Process (DP)

Plants:

Groundwater:

Surface water:

Surface Water Issues

Groundwater Issues

Uncertainties and Concerns

Benefits and Alternatives

Summary of Additional Aldicarb Data

Proposed Steps Forward

Message

From: Perlis, Robert [Perlis.Robert@epa.gov]
Sent: 4/24/2020 9:44:00 PM
To: Rate, Debra [Rate.Debra@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Koch, Erin [Koch.Erin@epa.gov]
Subject: FW: Requested OGC Guidance
Attachments: Aldicarb Citrus New Use Summary Papermj 1.21.20.docx

Debra:

Erin asked me to look at your aldicarb question(s). I have a couple of questions, but the bottom line is that

Ex. 5 AC/DP

Ex. 5 AC/DP

Sorry if my thoughts are somewhat scattered – and I'd be happy to talk about this with you next week.

Bob

Bob Perlis
Pesticides and Toxic Substances Law Office
Office of General Counsel
US EPA
(202) 564-5636

From: Koch, Erin <Koch.Erin@epa.gov>
Sent: Wednesday, April 22, 2020 12:02 PM
To: Perlis, Robert <Perlis.Robert@epa.gov>
Subject: FW: Requested OGC Guidance

Would you be able to give Debra initial advice on this one? I don't think the new folks are prepared to answer questions

Ex. 5 AC/DP

Ex. 5 AC/DP

Thanks,
Erin

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, April 21, 2020 1:38 PM
To: Koch, Erin <Koch.Erin@epa.gov>

Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: Requested OGC Guidance

Internal Deliberations

Hi Erin,

We want to keep OGC in the loop on a current new use action for aldicarb on citrus and to get your guidance on the next steps **Ex. 5 AC/DP** I have included some background information and projected next steps below. Also attached is the briefing memo that went up the chain earlier in the year for additional background.

Background:

We are working on an action for new uses for aldicarb on oranges and grapefruit in Texas and Florida. There is a tolerance for citrus that was left in place back in 2010 to address import tolerances. The domestic use on citrus was voluntarily cancelled in 2010 in order to bring risk to below agency LOC.

We have been working with HED, BEAD and EFED since last fall and prepared briefing papers up through Rick (Alex)

Ex. 5 AC/DP

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it
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Next Steps:

Ex. 5 AC/DP

Thank you in advance for any thoughts or guidance.
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/10/2020 8:51:45 PM
To: Donovan, William [donovan.william@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Request - additional "dietary runs" for aldicarb?

Hi Will,

Thank you so much for doing these extra dietary runs for us. I am not sure that we will need the numbers for the other population subgroups. We appreciate all of the work you have done so far on this action.

Many thanks!
Debra

From: Donovan, William <donovan.william@epa.gov>
Sent: Wednesday, June 10, 2020 8:54 AM
To: Rate, Debra <Rate.Debra@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Donovan, William <donovan.william@epa.gov>
Subject: RE: Request - additional "dietary runs" for aldicarb?

Hi Debra,

I have completed the runs you requested and have summarized the results in the attached file. Please let me know if you would like the results for all population subgroups, rather than just for children 1-2 (the most highly exposed subgroup), and I will send. Thanks,

Will

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, June 08, 2020 1:44 PM
To: Donovan, William <donovan.william@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Request - additional "dietary runs" for aldicarb?

Hi Will,

For #2, if you could add the import numbers you indicate for orange and grapefruit that would be good. Otherwise, I think those are the numbers we would like to see run.

Thank you so much for your help.
Debra

From: Donovan, William <donovan.william@epa.gov>
Sent: Monday, June 08, 2020 1:32 PM
To: Metzger, Michael <Metzger.Michael@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>
Subject: RE: Request - additional "dietary runs" for aldicarb?

Hi Debra,

Just want to be sure I am clear about the PCT values you would like me to run. My understanding is as follows (please correct if you want different values):

Ex. 5 Deliberative Process (DP)

Not

sure if you want that information included in run 2. Thanks,

Will

From: Metzger, Michael <Metzger.Michael@epa.gov>

Sent: Friday, June 05, 2020 5:40 PM

To: Rate, Debra <Rate.Debra@epa.gov>; Donovan, William <donovan.william@epa.gov>

Cc: Johnson, Marion <Johnson.Marion@epa.gov>

Subject: Re: Request - additional "dietary runs" for aldicarb?

Hi Will - Can you do these runs for RD. And, how long would it take?

Debra - DO you need a formal review or just an e-mail with numbers.

Thanks

Mike

From: Rate, Debra <Rate.Debra@epa.gov>

Sent: Thursday, June 4, 2020 4:58 PM

To: Metzger, Michael <Metzger.Michael@epa.gov>

Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: Request - additional "dietary runs" for aldicarb?

Hi Mike,

Ex. 5 Deliberative Process (DP)

Please let me know if your team would be able to perform these dietary runs for us.
Your time and efforts expended to generate these dietary runs is greatly appreciated!

Thanks,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 4/21/2020 4:08:52 PM
To: Collantes, Margarita [Collantes.Margarita@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Crowley, Matthew [Crowley.Matthew@epa.gov]; Waterworth, Rebecca [Waterworth.Rebeccah@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]
Subject: RE: Any updates on Aldicarb %CT?

Hi Margarita,

I was referring to the white paper that was submitted and provided to BEAD in March.

Thanks,
Debra

From: Collantes, Margarita <Collantes.Margarita@epa.gov>
Sent: Monday, April 20, 2020 5:38 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Crowley, Matthew <Crowley.Matthew@epa.gov>; Waterworth, Rebecca <Waterworth.Rebeccah@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>
Subject: RE: Any updates on Aldicarb %CT?

Hello Debra,

Could you please confirm whether any additional data will be submitted by the registrant. It was not clear whether the discussion below in reference to submission of additional data was now or previously.

Thank you,
margarita

From: Kaul, Monisha <Kaul.Monisha@epa.gov>
Sent: Monday, April 20, 2020 5:27 PM
To: Suarez, Mark <Suarez.Mark@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>
Cc: Crowley, Matthew <Crowley.Matthew@epa.gov>; Collantes, Margarita <Collantes.Margarita@epa.gov>; Waterworth, Rebecca <Waterworth.Rebeccah@epa.gov>
Subject: RE: Any updates on Aldicarb %CT?

Mark – Thanks for looping in the rest of the BEAD folks. I’ve tried to update our direction for the memo. Please share any other information that you’ve heard from RD in terms of appending our analysis.

All – it looks like Ex. 5 Deliberative Process (DP) I have highlighted RD’s current ask (below). I think we should find out when if/when any additional information will be submitted (also noted below). For now, the additional analysis should continue (Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Thanks,

Monisha

From: Suarez, Mark <Suarez.Mark@epa.gov>
Sent: Monday, April 20, 2020 3:59 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Collantes, Margarita <Collantes.Margarita@epa.gov>
Subject: RE: Any updates on Aldicarb %CT?

Debra,

Thank you for keeping me informed.

In consideration of the information below, I venture to say t

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Best,
Mark

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, April 20, 2020 3:47 PM
To: Suarez, Mark <Suarez.Mark@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Any updates on Aldicarb %CT?

Hi Mark,

I spoke with Marion and Shanta this afternoon. I think we are in agreement that we don't feel we are in a position to direct you on how BEAD should be conducting the review. With that said, we also do not want you to be needlessly running down rabbit holes trying to workout hypothetical scenarios that would not be used to regulate this product/use. Additionally, Marion spoke with Mike G. recently and Mike indicated t

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

On the call with the registrant, after providing them with the draft numbers and process we used to reach those %CT numbers, we said that they could submit more information for us to consider before we finalized those %CT. I think

Ex. 5 Deliberative Process (DP)

I will be contacting OGC today/tomorrow to make sure they are in the loop on the action and next steps and to get any additional guidance that they may be able to provide

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Please let me know if you want to discuss further with us.

Thanks.

Debra

From: Suarez, Mark <Suarez.Mark@epa.gov>
Sent: Thursday, April 16, 2020 5:03 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Any updates on Aldicarb %CT?

Debra,

We are working on it.

Ex. 5 Deliberative Process (DP)

Any thoughts on how that will happen? It will have to cover all registrations and all registrant that want the use. Have you guys started conversations with OGC, if not the registrant about how to structure that?

Best,
Mark

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, April 16, 2020 4:16 PM
To: Suarez, Mark <Suarez.Mark@epa.gov>
Subject: Any updates on Aldicarb %CT?

Hi Mark,

I hope you had a good break and you and family are staying safe and well (and sane?).

I wanted to follow up with you on the Aldicarb and the %CT memo – taking into account the white paper and production limits. Do you have a sense of when BEAD would be able to provide this memo to RD?

Thanks in advance!
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Donovan, William [donovan.william@epa.gov]
Sent: 6/10/2020 12:53:50 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Donovan, William [donovan.william@epa.gov]
Subject: RE: Request - additional "dietary runs" for aldicarb?
Attachments: Aldicarb DEEM Results june 2020.docx

Hi Debra,

I have completed the runs you requested and have summarized the results in the attached file. Please let me know if you would like the results for all population subgroups, rather than just for children 1-2 (the most highly exposed subgroup), and I will send. Thanks,

Will

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, June 08, 2020 1:44 PM
To: Donovan, William <donovan.william@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Request - additional "dietary runs" for aldicarb?

Hi Will,

For #2, if you could add the import numbers you indicate for orange and grapefruit that would be good. Otherwise, I think those are the numbers we would like to see run.

Thank you so much for your help.
Debra

From: Donovan, William <donovan.william@epa.gov>
Sent: Monday, June 08, 2020 1:32 PM
To: Metzger, Michael <Metzger.Michael@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>
Subject: RE: Request - additional "dietary runs" for aldicarb?

Hi Debra,

Just want to be sure I am clear about the PCT values you would like me to run. My understanding is as follows (please correct if you want different values):

Ex. 5 Deliberative Process (DP)

Will

From: Metzger, Michael <Metzger.Michael@epa.gov>
Sent: Friday, June 05, 2020 5:40 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Donovan, William <donovan.william@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>
Subject: Re: Request - additional "dietary runs" for aldicarb?

Hi Will - Can you do these runs for RD. And, how long would it take?

Debra - DO you need a formal review or just an e-mail with numbers.

Thanks

Mike

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, June 4, 2020 4:58 PM
To: Metzger, Michael <Metzger.Michael@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Request - additional "dietary runs" for aldicarb?

Hi Mike,

Ex. 5 Deliberative Process (DP)

Please let me know if your team would be able to perform these dietary runs for us.

Your time and efforts expended to generate these dietary runs is greatly appreciated!

Thanks,

Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/8/2020 5:40:35 PM
To: Metzger, Michael [Metzger.Michael@epa.gov]; Donovan, William [donovan.william@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Request - additional "dietary runs" for aldicarb?

Hi Mike,

There may be a need to have a formal "one pager" or similar once get the final BEAD review and/or we determine which pathway (not grant, denial, etc.) we will be taking to finish this action. But for now, with this request we are looking for more of an idea how the landscape is using numbers provided by the registrant – nothing formal – just some numbers.

Thanks.
Debra

From: Metzger, Michael <Metzger.Michael@epa.gov>
Sent: Friday, June 05, 2020 5:40 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Donovan, William <donovan.william@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>
Subject: Re: Request - additional "dietary runs" for aldicarb?

Hi Will - Can you do these runs for RD. And, how long would it take?
Debra - DO you need a formal review or just an e-mail with numbers.
Thanks
Mike

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, June 4, 2020 4:58 PM
To: Metzger, Michael <Metzger.Michael@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Request - additional "dietary runs" for aldicarb?

Hi Mike,

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Please let me know if your team would be able to perform these dietary runs for us.
Your time and efforts expended to generate these dietary runs is greatly appreciated!
Thanks,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Appointment

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 4/20/2020 11:44:30 AM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Discussion - Aldicarb next steps
Start: 4/20/2020 5:00:00 PM
End: 4/20/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Johnson, Marion; Adeeb, Shanta

Phone: **Ex. 6 PP - conference code/call in number**
Code: **Ex. 6 PP - conference code/call in number**

Hi Marion and Shanta,

I am going to need some help in answering Mark's question and to formulate a plan to move forward with the Aldicarb action with the company and OGC? I'm not yet comfortable on how to discuss/how the production cap could even work.....

Mark wants to know: "Working out the usage caps with the registrant will be an issue. It is causing some angst in BEAD. Any thoughts on how that will happen? It will have to cover all registrations and all registrant that want the use. Have you guys started conversations with OGC, if not the registrant about how to structure that?"

Thanks,
Debra

Message

From: Adeeb, Shanta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DD827C964D6042EB87B3D98B2539BFB9-ADEEB, SHAN]
Sent: 6/8/2020 10:43:31 AM
To: Rate, Debra [Rate.Debra@epa.gov]
Subject: RE: Request - additional "dietary runs" for aldicarb?

Hi Debra,

This would be challenging to manage under the best circumstances but working remotely has created additional barriers. I truly believe you have done a great job of navigating all the obstacles faced with this action. Please remember to give yourself grace, there are so many factors out of your control and all you can do is adapt and pivot as needed.

Shanta

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, June 04, 2020 4:58 PM
To: Metzger, Michael <Metzger.Michael@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Request - additional "dietary runs" for aldicarb?

Hi Mike,

Ex. 5 Deliberative Process (DP)

Please let me know if your team would be able to perform these dietary runs for us.
Your time and efforts expended to generate these dietary runs is greatly appreciated!
Thanks,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Hendrick, Lindsey [hendrick.lindsey@epa.gov]
Sent: 6/29/2020 6:00:50 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Donovan, William [donovan.william@epa.gov]
CC: Waterworth, Rebecca [Waterworth.Rebecca@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]; Crowley, Matthew [Crowley.Matthew@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Becker, Jonathan [Becker.Jonathan@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Aldicarb PCTn memo dated 29Jun2020
Attachments: PCTn for Aldicarb (098301) in FL_TX citrus_29Jun2020.pdf

Hi Debra and Will,

Here is the aldicarb PCTn memo. Please let us know if you have any questions about the recommended PCTn values provided in Table 4 and summarized in the conclusion. We'll be sure to share the official, signed memo as soon as possible.

Talk soon,
Lindsey

Lindsey R F Hendrick
OPP/BEAD/SIAB
703-347-8208

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/8/2020 12:07:08 AM
To: Gsell, Alyssa [Gsell.Alyssa@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Aldicarb meeting - 6/8/20 - Background / Agenda
Attachments: OGC outline 6-7-20.docx; One pager Aldicarb 9.8.19 dnr 2.docx

Hi Alyssa,

Attached is a one pager that we pulled together for our upper management with some background information on the current action. Also attached is a proposed agenda with some ideas for our discussion tomorrow.

Thanks,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Agenda 6/8/2020:

- Background: See one-pager.
- Current:
 - o Company rebutted BEAD analysis (and food-only assessment)
 - o Said that currently they are unable to produce enough aldicarb/product to treat that high % of the citrus.
 - o When asked how the product is applied to citrus, the company confirmed that the product cannot be applied at a depth below 1.5 inches in the citrus grove. (Labeling currently states that the product must be applied >2 inches.)



- Any insight into how the Administrator will view the different options?

Appendix - Reference

- **Summary**
- 1. AgLogic Chemical LLC is the only global producer of crop protection products containing aldicarb.
- 2. There are demonstrably insufficient quantities of AgLogic 15GG available to treat all the US citrus acres projected by EPA; production capacity of AgLogic 15GG is limited to 3,800,000 pounds per year.
- 3. Due to use on other crops, a maximum of 60% of plant capacity (2,280,000 lbs) could be allocated for use on oranges and grapefruit.
- 4. At the labeled use rate of 33 lbs/A, it would be possible to treat 69,091 acres which is 12.3% of the US orange and grapefruit acres.
- 5. At the reduced historical use rate of 28 lbs/A it would be possible to treat 81,429 acres which is 14.6% of the US orange and grapefruit acres.
- 6. To ensure that the use of AgLogic 15GG on oranges and grapefruit is controlled, a separate and distinct citrus only package and label would be sold to for Florida and Texas. This package and label will be specific for oranges and grapefruit and would be sold in Florida and Texas only.

Internal/Confidential/Deliberative
Aldicarb – Proposed Use on Citrus (Grapefruit and Oranges)
September 4, 2019

Background:

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity and to protect ground water.
- Aldicarb products are currently registered for use in agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. There are no registered residential uses of aldicarb.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.

Current Action:

- AgLogic Chemical LLC submitted an application on April 9, 2019 for registration of new uses of citrus (grapefruit and oranges) in Florida and Texas. The PRIA due date for this submission is July 15, 2020.
- There is no tolerance petition associated with the action as tolerances are established for grapefruit and orange, sweet, a use supported by Bayer prior to its decision to voluntarily cancel these and other uses in 2010.
- AgLogic Chemical LLC provided four (4) studies with the current action. They include the following:
 - White paper arguing the correct lateral flow velocity to use in assessment for drinking water.
 - White paper: Updated dietary (food + water) assessment (20 pages)
 - White paper: Updated dietary (food + water) assessment (272 pages – company's updated version)
 - White paper: Drinking water exposure assessment
- Citrus pests listed on the proposed label include Asian citrus psyllid (responsible for transmission of citrus greening); mites; aphids; whiteflies; and nematodes.

Benefits:

- Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives.
- Use of aldicarb tends to produce higher yields.
- Aldicarb is one of only four currently registered, non-fumigant nematicides.
- Aldicarb will provide another tool in the toolbox for growers to control Asian citrus psyllid. Based on the broad-spectrum nature of this carbamate, it is likely to kill the psyllid; however, its role in citrus greening and whether it is more efficacious than the 13 alternatives listed below is unknown.

Alternatives:

- Florida Citrus Production Guide ([[HYPERLINK](http://www.crec.ifas.ufl.edu/resources/production-guide/) "http://www.crec.ifas.ufl.edu/resources/production-guide/"]) list the following 12

alternative insecticides as having good control for psyllid: beta-cyfluthrin, chlorpyrifos, cyantraniliprole, dimethoate, fenpropathrin, fenpyroximate,

- phosmet, spinetoram, spirotetramat, thiamethoxam, tolfenpyrad, zeta-cypermethrin. In addition, EPA recently approved sulfoxaflor for use on citrus.

Ex. 5 Deliberative Process (DP)

Initial Conclusions:

Ex. 5 Deliberative Process (DP)

Additional Evaluation Areas:

Ex. 5 Deliberative Process (DP)

Next Steps:

Ex. 5 Deliberative Process (DP)

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/29/2020 2:39:08 PM
To: Crowley, Matthew [Crowley.Matthew@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Donovan, William [donovan.william@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Follow-up to BEAD/HED/RD meeting Tuesday 6/23/20 - Aldicarb PCTn for state refinement?

Thank you, Matt, for the update!

Debra

From: Crowley, Matthew <Crowley.Matthew@epa.gov>
Sent: Monday, June 29, 2020 10:38 AM
To: Rate, Debra <Rate.Debra@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Donovan, William <donovan.william@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Follow-up to BEAD/HED/RD meeting Tuesday 6/23/20 - Aldicarb PCTn for state refinement?

Hi everyone,

RD and HED will be sent the revised draft after noon today. (Lindsey Hendrick will be emailing it.)

Matthew Crowley, Acting Branch Chief
Science Information and Analysis Branch (SIAB)
EPA/OCSPP/OPP/BEAD
703-305-7606

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, June 29, 2020 10:13 AM
To: Metzger, Michael <Metzger.Michael@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Donovan, William <donovan.william@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Follow-up to BEAD/HED/RD meeting Tuesday 6/23/20 - Aldicarb PCTn for state refinement?

Hi,

I just wanted to check-in with all of you on the progress for the new PCTn numbers / dietary analysis following up from the meeting last Tuesday.

If possible, please let me know your status.

Thank you!

Debra

From: Rate, Debra
Sent: Tuesday, June 23, 2020 4:19 PM
To: Crowley, Matthew <Crowley.Matthew@epa.gov>
Cc: Kaul, Monisha <Kaul.Monisha@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Mark Suarez <Suarez.Mark@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Aldicarb Slides for Comment

Hi Matt,

I mostly updated the options/next steps slides and removed comments following the meeting on Thursday. (See attached) I agree that some of the slides will need to be updated as you described in your email below. However, Marion plans to send them forward to Mike G. with the caveat that may be some changes, but the message and options will likely be the same, to maintain the forward momentum for the action.

Thanks.
Debra

From: Crowley, Matthew <Crowley.Matthew@epa.gov>
Sent: Tuesday, June 23, 2020 3:32 PM
To: Suarez, Mark <Suarez.Mark@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Kaul, Monisha <Kaul.Monisha@epa.gov>
Subject: RE: Aldicarb Slides for Comment

Hi Debra and Marion,

Following our aldicarb today we remembered the slide deck going around and how that might be affected by today's discussion. Just wanted to check on the status of the slides. Are they on hold as far as briefing upper mgmt.?

BEAD is just a few days from having our issues reconciled with HED, and any slides can be revised after that.

Matthew Crowley, Acting Branch Chief
Science Information and Analysis Branch (SIAB)
EPA/OCSP/OPP/BEAD
703-305-7606

From: Suarez, Mark <Suarez.Mark@epa.gov>
Sent: Monday, June 15, 2020 9:07 AM
To: Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Waterworth, Rebekkah <Waterworth.Rebekkah@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>
Subject: Aldicarb Slides for Comment

All,

Here's a link to a shared version of the aldicarb briefing slides for BEAD comments.

[Draft Aldicarb Briefing Slides 061420 V2.pptx](#)

Regards,
Mark

Mark Suarez
Senior Scientist
Science Information and Analysis Branch
Biological and Economic Analysis Division
US EPA (Mail Code 7503P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

phone: 703-305-0120

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 4/13/2020 12:25:08 PM
To: Janelle Kay [Janelle@PyxisRC.com]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: AgLogic Follow-up to Feb. 24, 2020 call on aldicarb

Hi Janelle,

I hope you are staying safe, as well.

We are considering the discussion from the call and your follow up submission in our revised PCT assessment. If BEAD has any questions during their review process, we will be sure to reach out to you for assistance. We will be in touch once we have BEAD's PCT review.

Regards,
Debra

From: Janelle Kay <Janelle@PyxisRC.com>
Sent: Friday, April 10, 2020 9:35 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>
Subject: RE: AgLogic Follow-up to Feb. 24, 2020 call on aldicarb

Dear Debra,

I hope you are all staying well in these turbulent times. I wanted to check-in with you on the information we sent last month related to the PCT (a lot has changed in a month!) to see if you/BEAD had any questions, needed any additional information and how things were progressing.

Regards,

Janelle

JANELLE KAY



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
JANELLE@PYXISRC.COM

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, March 9, 2020 4:31 AM
To: Janelle Kay <Janelle@PyxisRC.com>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>
Subject: RE: AgLogic Follow-up to Feb. 24, 2020 call on aldicarb

Hi Janelle,

Thank you for the additional information. I will provide this to BEAD for their consideration in their %CT analysis.

We will let you know if we have any questions.

Regards,
Debra

From: Janelle Kay <Janelle@PyxisRC.com>

Sent: Friday, March 06, 2020 4:11 PM

To: Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Cc: Johnson, Marion <Johnson.Marion@epa.gov>

Subject: AgLogic Follow-up to Feb. 24, 2020 call on aldicarb

Dear Debra,

In follow-up to our call last Monday, attached is some additional information discussed regarding the amount of aldicarb that can be applied to oranges and grapefruit in FL and TX in order to refine the percent crop treated values. Let me know if you have any questions or need any additional information.

Regards,

Janelle

JANELLE KAY



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
JANELLE@PYXISRC.COM

Appointment

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/4/2020 1:48:07 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Gsell, Alyssa [Gsell.Alyssa@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Aldicarb - Citrus
Location: Microsoft Teams Meeting
Start: 6/8/2020 3:00:00 PM
End: 6/8/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Johnson, Marion; Gsell, Alyssa; Adeeb, Shanta

Hi Alyssa,

Marion and I would like to discuss with you the Aldicarb actions that were passed on to you by Bob on his way out. I want to reserve the time, now, but will provide a more detailed agenda prior to the meeting.

Please suggest an alternate meeting time if this time does not work for you schedule.

Thank you in advance for your time and guidance.

Debra

[Join Microsoft Teams Meeting](#)

Ex. 6 Conference Code

[Local numbers](#) | [Reset PIN](#) | [Learn more about Teams](#) | [Meeting options](#)

By participating in EPA hosted virtual meetings and events, you are consenting to abide by the agency's terms of use. In addition, you acknowledge that content you post may be collected and used in support of FOIA and eDiscovery activities.

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/29/2020 1:36:02 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: FW: revised slides - Aldicarb
Attachments: Draft Aldicarb Briefing Slides 062920.pptx

Sorry. Just realized Shanta was not copied.

From: Rate, Debra
Sent: Monday, June 29, 2020 9:35 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Subject: RE: revised slides - Aldicarb

Hi Marion and Shanta,

Attached is the draft slide deck for aldicarb. I haven't heard back from HED/BEAD yet, to know how their slides will need to be adjusted. However, I reordered per Catherine's suggestions and started to rework the Options/Recommendations slide.

I would appreciate any thoughts/edits you would have on these slides (esp. the time line for completion).....I don't quite know how long some steps may take or if this is what Catherine was looking for??

Thanks,
Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Thursday, June 25, 2020 5:03 PM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Goodis, Michael <Goodis.Michael@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: revised slides - Aldicarb

Thanks, Catherine!

We'll incorporate those suggestions and flesh out the questions, with more intent. Very quickly, however, Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Best regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2

U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
(703) 305-6788
johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Aubee, Catherine <Aubee.Catherine@epa.gov>
Sent: Thursday, June 25, 2020 4:17 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Goodis, Michael <Goodis.Michael@epa.gov>
Subject: RE: revised slides - Aldicarb

Hi Marion,

Thanks for the ping on this. We hope to brief Ed on this, so he can brief Alex, during the RD general the week of July 6th. Here are a few suggested clarifications to the slides:

- Slides 3 and 14-16 seem to contain the key messages for upper management. I suggest beginning with these and then keeping the rest as additional background.

- On options: **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Best,
Catherine

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Thursday, June 25, 2020 3:17 PM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>
Subject: FW: revised slides - Aldicarb

Catherine – Just checking in. Any updates? My team was asking during our staff meeting today, so I told them I would check, notwithstanding that the senior management transitions are in full effect. Many thanks!

Regards,

MJJ

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
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(703) 305-6788
johnson.marion@epa.gov

Visit: <http://www.epa.gov/pesticides>

From: Johnson, Marion

Sent: Tuesday, June 23, 2020 4:50 PM

To: Goodis, Michael <Goodis.Michael@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>

Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>

Subject: FW: revised slides - Aldicarb

Confidential/Deliberative
Not for Public Disclosure

Mike, Catherine:

Per our discussion in my general last Thursday, it was asked that I provide the aldicarb presentation slides prepared for the possibility of an upcoming briefing for senior management, prior to scheduling an actual briefing date. Enclosed you will find the latest briefing material, but realize that there are additional discussion points that are better articulated verbally that are not proposed in the slides. Additionally, there is an OGC question regarding the

Ex. 5 Deliberative Process (DP)

Nevertheless, realizing that changes are also occurring within the senior management ranks, let me know how you would best like to proceed, realizing that the PRIA date for this AgLogic submission is July 15, 2020. Ideally, I would like for the aldicarb interdisciplinary team to begin discussions with AgLogic to present them with the agency's findings to their most recent proposal and to discuss regulatory options (including withdrawal and denial). Of course, if we are able to provide this discussion to AgLogic at least 10, or so, days prior to the PRIA date, the issue of renegotiating to

Ex. 5 Deliberative Process (DP)

Therefore, let me know your thoughts, and I look forward to your feedback.

Best regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
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Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>

Sent: Friday, June 19, 2020 9:05 AM

To: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: revised slides - Aldicarb

Hi Marion, Shanta,

Attached are the aldicarb slides. I removed the comments and made some text updates to the summary and recommendations. I also split the HH slides into 2 slides to increase readability.

Please let me know what you think and if you think they are ready to be sent to the team and/or Mike G.
Thanks.

Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Aldicarb – Proposed New Uses

- Proposed use for oranges and grapefruit in Texas and Florida
 - Submitted April 9, 2019
- Apply granules in furrows 2 to 3 inches deep.
 - Apply only with granular applicators which use Positive Displacement Metering Units.
 - Cover or immediately deep-disk any granules spilled to ensure the granules are completely covered with at least 2 to 4 inches of soil.
- Apply granules in furrow beside individual trees and cover with at least 2 inches of soil by mechanical means.
- The maximum single application rate is 33 pounds product (4.95 lbs a.i.) per acre per year.
- Do not make more than one application per tree per year.
- Well set-back restrictions apply based on soil types.

Summary

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-
-
-

Ex. 5 Deliberative Process (DP)

Recommendations

~~Options: PRIA due date 7/15/2020~~

Ex. 5 Deliberative Process (DP)

Proposed Steps Forward

- Brief upper management on risks/assessments
- Communication again with the company regarding their request for refinement of the PCTn and rebuttal claims.
- Registration Division will again recommend withdrawal of the actions based on the expected exposures.
- Based on the current exposures/risk, a denial may need to be pursued.

Aldicarb - Background

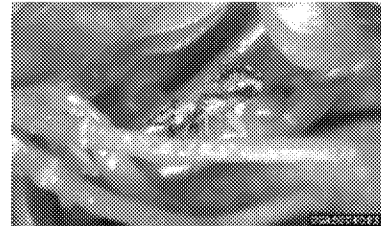
- N-methyl carbamate (NMC): to control certain insects, mites, and nematodes.
- There are no registered residential uses of aldicarb.
- Currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes.
- Restricted use pesticides due to acute oral, dermal and inhalation toxicity, and to protect ground water.

Aldicarb – Background (cont'd)

- **In 2010**, Bayer (the registrant at that time) voluntarily cancelled the domestic aldicarb uses on citrus (and potatoes), due to unacceptable dietary risk, especially to infants and young children.
 - Existing tolerances remained for citrus to allow for treated imports.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.
 - Risk estimates for dietary (food only) exposure below the level of concern (included imported citrus commodities only).
 - Drinking water risks were mitigated by appropriate well setbacks and with in-furrow applications.
 - By restricting application of aldicarb to a depth that eliminates runoff from a treated field, the agency no longer expected exposure or risk to terrestrial and aquatic plants, or to aquatic animals.

Benefits in Citrus

- Aldicarb controls a broad spectrum of pests⁴ and has a longer period of residual activity^{1,2} than most alternatives.
- Different mode of action (carbamate; IRAC group 1A) than currently registered alternatives for psyllid control on citrus
- Low impact on natural enemies⁴, compared to currently registered alternatives³
- Based on historical usage patterns of aldicarb in citrus, growers are likely to use aldicarb for control of Asian citrus psyllid (ACP) – the insect vector of the pathogen that causes the disease citrus greening or Huanglongbing (HLB).
- Registrant claims root growth and plant health claims but lacked supporting evidence – and suggests low insecticidal benefits.



An adult Asian citrus psyllid
1/6 to 1/8 inch long
Photo by David Hall, USDA
Agricultural Research Service
Bugwood.org

¹ Qureshi et al. 2014 *PLoS ONE*; ² Childers et al. 1987 *J. Econ. Entomol.*; ³ Diepenbrock et al. 2019 IFAS Extension;
⁴ Rogers 2008 *Citrus Industry*

Huanglongbing = yellow dragon disease

Images from bugwood.org (hosted by the University Georgia) can be used as long as they are properly attributed. Only commercial uses are not allowed unless permission of the "author" is given.

Alternatives in Citrus

- Over 30 currently registered insecticides for ACP control in citrus.
 - Aldicarb, as a carbamate (IRAC group 1A), is a different mode of action compared to alternatives; carbaryl is the only registered alternative in the same group.
- For ACP control, aldicarb is less efficacious than some alternative insecticides but provides longer residual control.
- Aldicarb is likely to be quickly readopted in rotational programs in an effort to control ACP - alternative chemicals do not provide adequate control.

5

Ex. 5 Deliberative Process (DP)

Projected Percent Crop Treated (PCTn)

PCTn is the estimated percent crop treated (PCT) for a proposed new use, developed with historical usage data of market leader pesticide(s)

National analysis not appropriate

- Proposed new use is for FL and TX only
- >80% grapefruit and orange acres are in these two states
- Juice oranges grown primarily in FL

State-level PCTn for aldicarb:

Crop	State	Minimum PCTn	Maximum PCTn
Grapefruit	FL	85%	90%
Grapefruit	TX	90%	100%
Oranges (and Juice)	FL	90%	90%

AgLogic Comments and EPA Responses

- *PCTn estimates should be based on “the most current and reliable statistics, such as those provided by the USDA National Agricultural Statistics Service (NASS)”*
 - Derived from usage data available from Kynetec (Best Available Data)
 - Annual survey
 - Pest-specific data
 - Data for last 5 years of previous registration available (2007-2011)
- *PCTn should be analyzed using Florida and Texas citrus production data;*
 - Developed using state-level data
 - Interpret as percentage of crop acres grown in FL and TX that may be treated with aldicarb should the proposed new use be approved
- *Imported juice concentrate does not contain aldicarb*
 - EPA assumed 100% of imported product was treated when calculating orange PCTn
- *An appropriate PCTn for of all US orange and grapefruit acreage is 14.6%*
 - Registrant-proposed PCTn calculated using national crop production data

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Ex. 5 Deliberative Process (DP)

Aldicarb Human Health Risks

- A highly refined acute dietary (food only) exposure assessment was conducted.
- Food only risk (Orange Juice is the risk driver):

-

Ex. 5 Deliberative Process (DP)

-

Aldicarb Human Health Risks (cont'd)

- Food only using drinking water level of comparison (DWLOC) approach :
 - Thus, a DWLOC level is determined by including water concentrations with food residues sufficient to give a risk level of approximately 100% aPAD for the most highly exposed population subgroup.

Ex. 5 Deliberative Process (DP)

Aldicarb Ecological Risks

Based on previous risk assessments –

Ex. 5 Deliberative Process (DP)

Birds and Mammals:

- Primary risk is for birds and mammals consuming granules (1 granule can cause mortality).
 - Numerous incidents involving mortality from accidental or misuse of aldicarb. Modeling with 99.9% incorporation of granules produced RQs that exceeded the LOCs for small and medium birds and mammals.

Aquatic Organisms:

- Most aquatic organism acute and all chronic RQs exceeded all LOCs for all registered labeled uses of aldicarb.

Terrestrial Organisms:

- Highly acutely toxic to honey bees on a contact basis.
 - Although aldicarb has only granule applications which limits contact with bees, it is a systemic pesticide

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Drinking Water - Surface Water

FLcitrusSTD scenario file was used to model the citrus use. Considering the different soil incorporation depths, the 1-day average EDWCs are presented below:

Soil Depth	1-day average EDWC (ppb)	DWLOC (0.87 ppb) as percent of 1-day average EDWC	EDWC as multiple of DWLOC (0.87 ppb)
2 inches	39.2	2.22%	45
3 inches	17.0	5.12%	19.5
6 inches	4.24	20.52%	4.9

- Depending on the soil incorporation depth, the resulting EDWCs represent between 4.87 to 45 times the DWLOC (0.87 ppb).
- The citrus use label restricts use to only Florida and Texas. Since aldicarb is only registered for use on cotton and peanuts in FL and TX, the use of regional PCA was used to refine the EDWCs.

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Surface Water: Regionally Refined

The regional PCAs at HUC-2 scale for Florida and Texas on cotton, orchard and vegetables combined are shown below:

HUC-2	PCA cotton+orchard+vegetables
3 (Florida)	14.2%
12 (Texas)	20.8%
13 (Texas)	3%

The adjusted EDWCs for three regional PCA adjustments are tabulated below:

Soil Depth	1-day average EDWC (gpb)	HUC-2 3 (FL) 14.2%	HUC-2 12 (TX) 20.8%	HUC-2 13 (TX) 3%
2 inches	39.2	5.57	8.15	1.18
3 inches	17.0	2.41	3.54	0.51
6 inches	4.24	0.60	0.88	0.13

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Drinking Water - Groundwater

- GW drinking water concentrations modeled using Florida Central Ridge Scenario (co-located with citrus use) with 0.5 ft/day groundwater flow velocity.
- Additional characteristics including aldicarb's sensitivity to water pH levels and co-location with drinking water watersheds and orchards could be considered (degrades faster with increasing pH).
- For levels below the DWLOC, required well setbacks: 700 ft at pH6; 175 ft at pH7; 50 ft at pH 8.

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/23/2020 8:09:18 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb Slides for Comment

Hi Marion,

That sounds good. I will let Matt know what is happening and provide BEAD with the new draft of the slides.

Thanks.
Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Tuesday, June 23, 2020 4:04 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb Slides for Comment

Thanks, Debra! My personal intent was to move forward with the slides "as is", and let the RD/IO know that there could be slight modifications to the PCTn information, but that the overall proposal options will remain the same. I'm hoping to provide the slides to the RD/IO before the close of business today. However, let me know if you have additional thoughts.

Best,

MJJ

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
(703) 305-6788
johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, June 23, 2020 4:00 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Aldicarb Slides for Comment

Hi Marion,

I agree that some of the slides will need to be updated. Is it worth sending them the revised draft slides, now, and BEAD can update when ready? Or would it be better for us to update when they give us the new information?

Thanks,
Debra

From: Crowley, Matthew <Crowley.Matthew@epa.gov>
Sent: Tuesday, June 23, 2020 3:32 PM
To: Suarez, Mark <Suarez.Mark@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Kaul, Monisha <Kaul.Monisha@epa.gov>
Subject: RE: Aldicarb Slides for Comment

Hi Debra and Marion,

Following our aldicarb today we remembered the slide deck going around and how that might be affected by today's discussion. Just wanted to check on the status of the slides. Are they on hold as far as briefing upper mgmt.?

BEAD is just a few days from having our issues reconciled with HED, and any slides can be revised after that.

Matthew Crowley, Acting Branch Chief
Science Information and Analysis Branch (SIAB)
EPA/OCSP/OPP/BEAD
703-305-7606

From: Suarez, Mark <Suarez.Mark@epa.gov>
Sent: Monday, June 15, 2020 9:07 AM
To: Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>
Subject: Aldicarb Slides for Comment

All,

Here's a link to a shared version of the aldicarb briefing slides for BEAD comments.

[Draft Aldicarb Briefing Slides 061420 V2.pptx](#)

Regards,
Mark

Mark Suarez
Senior Scientist
Science Information and Analysis Branch
Biological and Economic Analysis Division
US EPA (Mail Code 7503P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

phone: 703-305-0120

Appointment

From: Collantes, Margarita [Collantes.Margarita@epa.gov]
Sent: 3/20/2020 7:36:06 PM
To: Lenners, Alicia [lenners.alicia@epa.gov]; Waterworth, Rebecca [Waterworth.Rebecca@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Jarboe, Stephen [Jarboe.Steve@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
CC: Crowley, Matthew [Crowley.Matthew@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]
Subject: Aldicarb PCT analysis
Location: Skype Meeting
Start: 3/24/2020 7:30:00 PM
End: 3/24/2020 8:30:00 PM
Show Time As: Tentative

Required Attendees: Lenners, Alicia; Waterworth, Rebecca; Hansel, Jeana; Suarez, Mark; Jarboe, Stephen; Rate, Debra; Adeeb, Shanta
Optional Attendees: Crowley, Matthew; Kaul, Monisha

Join Skype Meeting

Trouble Joining? [Try Skype Web App](#)

Join by phone

Toll number: (Dial-in Number)

English (United States)

[Find a local number](#)

Conference ID:

[Forgot your dial-in PIN?](#) | [Help](#)

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 3/20/2020 6:41:51 PM
To: Collantes, Margarita [Collantes.Margarita@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb New use action - Follow-up information from conference call 2/24/20.

Sounds good.

From: Collantes, Margarita <Collantes.Margarita@epa.gov>
Sent: Friday, March 20, 2020 9:27 AM
To: Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb New use action - Follow-up information from conference call 2/24/20.

Hello Debra,

I will be setting up a short conference call with RD and the BEAD Aldicarb Team for early next week to make sure that we are all on the same page regarding BEAD's approach **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP) to provide PCT information in response to registrant's request. I will invite you and Shanta, but please forward invite to anyone else from RD whom I missed.

Thank-you,
margarita

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, March 19, 2020 5:05 PM
To: Collantes, Margarita <Collantes.Margarita@epa.gov>
Subject: RE: Aldicarb New use action - Follow-up information from conference call 2/24/20.

That's perfect. Thank you!

From: Collantes, Margarita <Collantes.Margarita@epa.gov>
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To: Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb New use action - Follow-up information from conference call 2/24/20.

Debra,

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From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, March 19, 2020 3:46 PM
To: Collantes, Margarita <Collantes.Margarita@epa.gov>
Subject: RE: Aldicarb New use action - Follow-up information from conference call 2/24/20.

Hi Margarita,

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Thanks,
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Please let us know.
Thank you.
Debra

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To: Rate, Debra <Rate.Debra@epa.gov>
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Ex. 6 PP - personal phone

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To: Collantes, Margarita <Collantes.Margarita@epa.gov>
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Subject: RE: Aldicarb New use action - Follow-up information from conference call 2/24/20.

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From: Kaul, Monisha <Kaul.Monisha@epa.gov>
Sent: Tuesday, March 10, 2020 8:11 PM
To: Collantes, Margarita <Collantes.Margarita@epa.gov>
Subject: RE: Aldicarb New use action - Follow-up information from conference call 2/24/20.

Hello Margarita,

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I don't have a request for the benefits either.

You could also check with Carolyn – she may have entered on our end – or ask Debra.

Thanks,

Monisha

From: Collantes, Margarita <Collantes.Margarita@epa.gov>
Sent: Tuesday, March 10, 2020 4:40 PM
To: Kaul, Monisha <Kaul.Monisha@epa.gov>
Subject: FW: Aldicarb New use action - Follow-up information from conference call 2/24/20.

Monisha,

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p.s. I entered the attached data into the G:drive

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Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Collantes, Margarita <Collantes.Margarita@epa.gov>
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Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Collantes, Margarita [Collantes.Margarita@epa.gov]
Sent: 3/20/2020 1:26:37 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb New use action - Follow-up information from conference call 2/24/20.

Hello Debra,

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Ex. 6 PP - personal phone

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You could also check with Carolyn – she may have entered on our end – or ask Debra.

Thanks,

Monisha

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Sent: Tuesday, March 10, 2020 4:40 PM
To: Kaul, Monisha <Kaul.Monisha@epa.gov>
Subject: FW: Aldicarb New use action - Follow-up information from conference call 2/24/20.

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Thanks
Margarita

p.s. I entered the attached data into the G:drvie

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Sent: Tuesday, March 10, 2020 2:54 PM

To: Suarez, Mark <Suarez.Mark@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>

Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Collantes, Margarita <Collantes.Margarita@epa.gov>

Subject: Aldicarb New use action - Follow-up information from conference call 2/24/20.

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Thank you for all of your work on this action and please let us know if there is anything more you need from us or the registrant to complete this action.

Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 3/19/2020 5:59:17 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb New use action - Follow-up information from conference call 2/24/20.

Hi Marion,

BEAD got all of the information two weeks ago. Upon prodding Margarita only asked for the BEAN to be sent again last week and a timeline this week. I sent an email earlier and asked by end of April. But I will let her know that upon further consultation we would prefer mid-April.

Sorry about that.
Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Thursday, March 19, 2020 1:56 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb New use action - Follow-up information from conference call 2/24/20.

Debra,

I would think that a lot depends upon when we believe we can get the registrant's response up to them; it's my understanding that that has not happened due to the unscheduled telework activities. That said, I think we should shoot for the middle of April, if not the first week of April.

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
(703) 305-6788
johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, March 19, 2020 10:22 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Aldicarb New use action - Follow-up information from conference call 2/24/20.

Hi Marion and Shanta,

Any thoughts on when to ask BEAD for the final %CT memo for the Aldicarb? The PRIA due date is July 2020. However, if BEAD **Ex. 5 Deliberative Process (DP)** we still have a lot of work to catch up with EFED and HED.

If you have a chance, please let me know.
Debra

From: Rate, Debra
Sent: Tuesday, March 17, 2020 4:01 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Aldicarb New use action - Follow-up information from conference call 2/24/20.

Hi Marion and Shanta,

Can you help me to provide a time-line for the updated BEAD review. Balance what we need vs. what is reasonable to expect?

Thoughts are greatly appreciated.

Thanks.

Debra

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To: Rate, Debra <Rate.Debra@epa.gov>
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Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 6/23/2020 2:25:51 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb PCTn Memo with Author Responses to BC/OGC comments

Okay.

MJJ

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
(703) 305-6788
johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, June 23, 2020 10:22 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Aldicarb PCTn Memo with Author Responses to BC/OGC comments

Hi Marion / Shanta,

I got this email from Mark just before the 10:00am call.

I only time I seem to be able to find on the team's (BEAD/RD/HED) calendars is 12:30 pm. So I apologize in advance.

Unless you have any thoughts on this, I will send out the invite in a few minutes.

Thanks,
Debra

From: Suarez, Mark <Suarez.Mark@epa.gov>
Sent: Tuesday, June 23, 2020 9:26 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Crowley, Matthew <Crowley.Matthew@epa.gov>
Subject: FW: Aldicarb PCTn Memo with Author Responses to BC/OGC comments

Debra,

We received the email below from Angela.

Can we have a short team meeting today or tomorrow to sort this out? We don't need everyone, but HED, RD, and BEAD had representation, we should be able to resolve this. Specifically, Angela has the impression that HED may be running the assessment for the OJ driver using national orange PCT numbers.

Thanks,
Mark

From: Huskey, Angela <Huskey.Angela@epa.gov>
Sent: Monday, June 22, 2020 3:28 PM
To: Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>
Cc: Hansel, Jeana <Hansel.Jeana@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Koch, Erin <Koch.Erin@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>
Subject: RE: Aldicarb PCTn Memo with Author Responses to BC/OGC comments

Hi Rebecca,

Thanks for this document. I haven't seen these documents before, so it's helpful to read through and see how the approach has adapted over time. I don't know that the issue with the current memo is regarding the SOP; it seems that

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Please let me know if you'd like to discuss.

Thanks,
Angela

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/22/2020 3:33:36 PM
To: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Automatic reply: revised slides - Aldicarb

I am currently out of the office, but will be returning Tuesday 6/23/2020. I will respond to your emails at that time.

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 6/19/2020 1:35:12 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: revised slides - Aldicarb

Will do. . .

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
(703) 305-6788
johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Friday, June 19, 2020 9:05 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: revised slides - Aldicarb

Hi Marion, Shanta,

Attached are the aldicarb slides. I removed the comments and made some text updates to the summary and recommendations. I also split the HH slides into 2 slides to increase readability.

Please let me know what you think and if you think they are ready to be sent to the team and/or Mike G.

Thanks.

Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Adeeb, Shanta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DD827C964D6042EB87B3D98B2539BFB9-ADEEB, SHAN]
Sent: 3/11/2020 6:26:48 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
Subject: RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

Thanks

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Wednesday, March 11, 2020 1:50 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

Fyi. . . No action necessary as ITRMD/FOIA has been actively involved and leading the request for the U.S. to release the original registrant's data submission.

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
(703) 305-6788
johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Larry Hodges <larryhodges@meycorp.com>
Sent: Wednesday, March 11, 2020 12:19 PM
To: Budd, Karina <Karina.Budd@agriculture.gov.au>
Cc: Reichstein, Ian <ian.Reichstein@agriculture.gov.au>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; IMCEAMAILTO-Ingram+2EEarl+40epa+2Egov@namprd04.prod.outlook.com; Furlow, Calvin <Furlow.Calvin@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Antoine Puech <antoinepuech@meycorp.com>
Subject: RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

Dear Karina,

Thanks for helping me join the CCPR-Priorities-2019 electronic working group (EWG). I reviewed the listing for the 2021 Periodic Review and see that aldicarb (117) is tentatively scheduled for review in 2021. A note in the comments section requested advice on the commodities.

The commodities are: Citrus (oranges, grapefruit, lemons, limes), Cotton, Dry Beans, Peanuts, Soybeans, Sugar Beets, Sweet Potatoes. I have also listed these on the attached 2021 Periodic Review Excel document.

We are still trying to arrange for submission of the supporting toxicology and residue studies to the JMPR. However, as explained in previous emails, AgLogic Chemical LLC is a generic registrant and, as allowed by US law, our aldicarb registration is supported by toxicology and residue data that were developed and

submitted to the US Environmental Protection Agency (EPA) by aldicarb's previous registrant, Bayer CropScience. AgLogic is not allowed to have copies of the actual studies that support registration and, therefore, despite our best intentions, we are not able to submit these studies to the JMPR for review.

Although Bayer will not consent to the EPA's direct release of aldicarb toxicology and residue studies to the JMPR, the EPA may be able to provide the studies directly to the CCPR without agreement from Bayer if done so through a Freedom of Information Request (FOIA).

I suggest that we proceed with FOIA requests for the toxicology and residue studies or, alternatively, since the EPA already has the supporting studies, the aldicarb reviews could be written by the EPA's residue and toxicology experts that participate in the JMPR.

Your help with an appropriate way forward will be most appreciated.

Best Regards,
Larry Hodges, Ph.D.
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800

From: Budd, Karina <Karina.Budd@agriculture.gov.au>
Sent: Monday, November 4, 2019 4:08 PM
To: Larry Hodges <larryhodges@meycorp.com>
Cc: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; Budd, Karina <Karina.Budd@agriculture.gov.au>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; doherty.michael@epa.gov; IMCEAMAILTO-Ingram+2EEarl+40epa+2Egov@namprd04.prod.outlook.com; Furlow.Calvin@epa.gov; Johnson.Marion@epa.gov; Antoine Puech <antoinepuech@meycorp.com>
Subject: FW: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR [SEC=UNCLASSIFIED]

Dear Larry,

Ian Reichstein is on extended leave and I am managing the CCPR Priorities working group. Regarding this schedule, aldicarb has been moved from the 2020 periodic review to the 2021 periodic review (see attached).

Aldicarb was not included in the recent JMPR data call in for JMPR review in 2020:
http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/2020_Call_for_data_Final.pdf

I encourage you to join the CCPR-Priorities-2019 electronic working group (EWG), where updated priority and schedule documents will be loaded.

The EWG platform link is at: <http://forum.codex-alimentarius.net/index.php>

You will need to register for the online platform: <http://forum.codex-alimentarius.net/viewtopic.php?f=13&t=110>

The Priorities EWG is titled "*Establishment of CCPR schedules and priority list for the evaluation of pesticides by JMPR*".

The online invitation to this forum is at

http://www.fao.org/fileadmin/user_upload/codexalimentarius/invitations/Australia-CCPR-EWG%20PL%20invitation%202019.pdf

If you have any problems with this process, there are videos

(<https://www.youtube.com/watch?v=EJn9k7wNSwk&feature=youtu.be>) and your national Codex contact point should be able to provide assistance.

Thankyou for following up with us, and I look forward to further updates closer to the next meeting of CCPR.

Kind regards,

Karina Budd

Karina Budd
Director - Residue Chemistry and Laboratory Performance Evaluation Section
National Residue Survey | Exports Division | Department of Agriculture
Phone +61 2 6272 5795 | Mobile +61 408 695 904 |
Email karina.budd@agriculture.gov.au
18 Marcus Clarke Street, Canberra ACT 2601 Australia
GPO Box 858, Canberra ACT 2601 Australia

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 7/7/2020 12:14:38 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb Meeting this Morning

Hi Marion and Shanta,

Sorry about the timing. This was the only time pre-briefing that I was able to get most team members.

The 3 pm meeting for the briefing was the only time she was able to find that got almost everyone of the team.

Let me know if you want me to cancel either one. Since it was as the end of the day, I told her to send it out and we could see how it falls out today.

Thanks,
Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Tuesday, July 07, 2020 8:07 AM
To: Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb Meeting this Morning
Importance: High

Debra, Shanta - I think that we should have Virna reschedule the metaflumizone meeting in favor of the aldicarb pre-meeting this morning at 8:30 a.m. I think that the scheduling for the aldicarb with Mike is probably too short notice, but I guess we'll have to work through it. Let me know your quick thoughts.

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
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Office of Pesticide Programs
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johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 7/7/2020 12:09:05 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb Meeting this Morning

Thanks, I see that the metaflumizone meeting has already been canceled!

MJJ

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
(703) 305-6788
johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Johnson, Marion
Sent: Tuesday, July 7, 2020 8:07 AM
To: Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb Meeting this Morning
Importance: High

Debra, Shanta - I think that we should have Virna reschedule the metaflumizone meeting in favor of the aldicarb pre-meeting this morning at 8:30 a.m. I think that the scheduling for the aldicarb with Mike is probably too short notice, but I guess we'll have to work through it. Let me know your quick thoughts.

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
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johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 7/6/2020 9:08:23 PM
To: Kaul, Monisha [Kaul.Monisha@epa.gov]; Crowley, Matthew [Crowley.Matthew@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb Slides for Comment
Attachments: Draft Aldicarb Briefing Slides 070120 - Revised.pptx

Hi Monisha,

No other changes have been made since my last update that I saved to send out with the meeting briefing invite. It is attached here. Let me know if you have any changes and I will get them to Anita Coleman to update the calendar invite tomorrow.

Thanks.
Debra

From: Kaul, Monisha <Kaul.Monisha@epa.gov>
Sent: Monday, July 06, 2020 4:57 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb Slides for Comment

Those slides were in my email. Can you please resend the link and/or file? Thanks!

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, July 06, 2020 4:50 PM
To: Kaul, Monisha <Kaul.Monisha@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb Slides for Comment

Hi Monisha,

Did you download those from the OneDrive today? I made some changes to the slide deck on the OneDrive today, following an 11:30 meeting with Shanta and Marion.

Debra

From: Kaul, Monisha <Kaul.Monisha@epa.gov>
Sent: Monday, July 06, 2020 4:42 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb Slides for Comment

Hi Debra,

Checking to confirm these are the most recent slides for the upcoming briefing. Please let me know.

Thanks,

Monisha

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, June 23, 2020 4:19 PM
To: Crowley, Matthew <Crowley.Matthew@epa.gov>
Cc: Kaul, Monisha <Kaul.Monisha@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: Aldicarb Slides for Comment

Hi Matt,

I mostly updated the options/next steps slides and removed comments following the meeting on Thursday. (See attached) I agree that some of the slides will need to be updated as you described in your email below. However, Marion plans to send them forward to Mike G. with the caveat that may be some changes, but the message and options will likely be the same, to maintain the forward momentum for the action.

Thanks.

Debra

From: Crowley, Matthew <Crowley.Matthew@epa.gov>
Sent: Tuesday, June 23, 2020 3:32 PM
To: Suarez, Mark <Suarez.Mark@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Kaul, Monisha <Kaul.Monisha@epa.gov>
Subject: RE: Aldicarb Slides for Comment

Hi Debra and Marion,

Following our aldicarb today we remembered the slide deck going around and how that might be affected by today's discussion. Just wanted to check on the status of the slides. Are they on hold as far as briefing upper mgmt.?

BEAD is just a few days from having our issues reconciled with HED, and any slides can be revised after that.

Matthew Crowley, Acting Branch Chief
Science Information and Analysis Branch (SIAB)
EPA/OCSP/OPP/BEAD
703-305-7606

From: Suarez, Mark <Suarez.Mark@epa.gov>
Sent: Monday, June 15, 2020 9:07 AM
To: Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>
Subject: Aldicarb Slides for Comment

All,

Here's a link to a shared version of the aldicarb briefing slides for BEAD comments.

Regards,
Mark

Mark Suarez
Senior Scientist
Science Information and Analysis Branch
Biological and Economic Analysis Division
US EPA (Mail Code 7503P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

phone: 703-305-0120

Message

From: Janelle Kay [Janelle@PyxisRC.com]
Sent: 3/6/2020 9:11:11 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]
Subject: AgLogic Follow-up to Feb. 24, 2020 call on aldicarb
Attachments: 20200306 Additional information Related to Aldicarb Use on Citrus_final.pdf

Dear Debra,

In follow-up to our call last Monday, attached is some additional information discussed regarding the amount of aldicarb that can be applied to oranges and grapefruit in FL and TX in order to refine the percent crop treated values. Let me know if you have any questions or need any additional information.

Regards,

Janelle

JANELLE KAY



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
JANELLE@PYXISRC.COM

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 2/28/2020 8:33:18 PM
To: Suarez, Mark [Suarez.Mark@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]
CC: Johnson, Hope [Johnson.Hope@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb: Follow-up questions from AgLogic on PCT numbers, acreage, etc.?

Thank you, Mark!

From: Suarez, Mark <Suarez.Mark@epa.gov>
Sent: Friday, February 28, 2020 3:30 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>
Cc: Johnson, Hope <Johnson.Hope@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb: Follow-up questions from AgLogic on PCT numbers, acreage, etc.?

Debra,

Please see my responses below.

Thank you,
Mark

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Friday, February 28, 2020 7:54 AM
To: Suarez, Mark <Suarez.Mark@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>
Cc: Johnson, Hope <Johnson.Hope@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb: Follow-up questions from AgLogic on PCT numbers, acreage, etc.?

Hi Mark and Lindsey,

AgLogic has been preparing their response in follow up to the call on Monday and had a few questions for us. I am hoping that you will be able to help me provide answers for them. The questions are as follows:

- For PCT, are we correct that the numbers used in the assessment are for % treated of entire US? (Or, is it % treated of FL/TX?)
OPP analyzed citrus usage at both at the national level and for the proposed geographic limitations (FL and TX). The average/maximum PCTn's projected for grapefruit at the national and FL and TX were 80/90 and 80/90(FL) or 75/100(TX), respectively. For orange, average/maximum PCTn's were projected nationally as 60/65 and 80/85 in Florida.
- AgLogic has been trying to gather information on the products used for comparison, could you provide the references to the state databases used for the replacement products to determine PCT?
OPP obtained market leader usage information from Kynetec and USDA NASS for the purposes of this PCTn analysis. The Kynetec are proprietary, but you may freely access the USDA NASS data. The following link will take you to the NASS usage data for grapefruit, lemon, and orange used in the analysis – <https://quickstats.nass.usda.gov/results/312B93B1-B038-30BC-B868-C84F5C76F73F>.
- With respect to the replacement products, has EPA taken into account the number of applications for a particular product in determining acreage? AgLogic hasn't been able to verify the values reported (e.g. 90% grapefruit treated) and wanted to make sure that multiple applications resulted in overstating the acres treated.

OPP uses reported PCT values for the market leaders to develop the PCTn. The reported PCT is the (Base Acres Treated)/(Crop Acres Grown). Therefore, the concern expressed about multiple applications within a year inflating the PCT are not warranted.

Thank you in advance for your assistance in providing responses for the registrant.
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 2/25/2020 1:07:17 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Meeting notes/highlights from Aldicarb meeting 2/24/20
Attachments: BEAD and RD Aldicarb Meeting 2-24-20 notes and next steps.docx

Hi Marion and Shanta,

Attached are a few highlights from the aldicarb meeting and next steps. Please feel free to edit and add to as appropriate.

Thanks,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 2/24/2020 2:54:32 PM
To: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
CC: Rate, Debra [Rate.Debra@epa.gov]
Subject: FW: Aldicarb discussion with registrant - %CT

Shanta:

FYI. . . when hitting "reply all", I forgot to include you in the response.

MJJ

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
(703) 305-6788
johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Johnson, Marion
Sent: Monday, February 24, 2020 9:17 AM
To: Goodis, Michael <Goodis.Michael@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Cc: Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: RE: Aldicarb discussion with registrant - %CT

Mike,

Sure thing! We just wanted you to have a courtesy invitation, so that you and the Program IO were reminded of the current aldicarb status with the registrant. We'll keep you updated on the occurrences.

Regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788
johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Monday, February 24, 2020 8:51 AM
To: Rate, Debra <Rate.Debra@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Aubee, Catherine <Aubee.Catherine@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>
Subject: RE: Aldicarb discussion with registrant - %CT

Just confirming with you that considering the topic, Dan, Catherine or I are not planning to attend this meeting. let us know how it turns out. thanks

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

-----Original Appointment-----

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Wednesday, February 19, 2020 7:04 AM
To: Rate, Debra; Johnson, Hope; Suarez, Mark; Hendrick, Lindsey; Jarboe, Stephen; Adeeb, Shanta; Johnson, Marion; Kaul, Monisha
Cc: Hansel, Jeana; Waterworth, Rebecca; Collantes, Margarita; Becker, Jonathan; Goodis, Michael; Rosenblatt, Daniel; Aubee, Catherine
Subject: Aldicarb discussion with registrant - %CT
When: Monday, February 24, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomPYS7100/Potomac-Yard-One

Hi All,

The time has been confirmed with the registrant. I will be following up shortly (via email) with a white paper that the registrant has prepared concerning their analysis on %CT. I will also keep the group updated with any additional topics are raised for discussion at the meeting.

I will set up the following a call in numbers for the meeting

Phone: 1 (202) 991-0477
Code: 9621594

Thanks,
Debra

Message

From: Adeeb, Shanta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DD827C964D6042EB87B3D98B2539BFB9-ADEEB, SHAN]
Sent: 2/24/2020 1:25:08 PM
To: Rate, Debra [Rate.Debra@epa.gov]
Subject: RE: Your thoughts for the aldcarb meeting Monday?

Thanks Debra

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, February 24, 2020 8:10 AM
To: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Your thoughts for the aldcarb meeting Monday?

I briefly talked with Mark S. on Friday before I sent the last note to Janelle.

Ex. 5 Deliberative Process (DP) . 5 Deliberative Process (DP)

I have booked the room starting at 10:30 am this morning. I'll let you know what I hear from Mark.

Debra

From: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Sent: Monday, February 24, 2020 8:04 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Your thoughts for the aldcarb meeting Monday?

Ex. 5 Deliberative Process (DP) Is there anything we need to discuss before the meeting today?

Shanta

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Friday, February 21, 2020 2:38 PM
To: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Your thoughts for the aldcarb meeting Monday?

Hi Shanta,

Ex. 5 Deliberative Process (DP)

Thanks.
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division

U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Janelle Kay [Janelle@PyxisRC.com]
Sent: 2/21/2020 9:58:19 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Ann Tillman [Ann@PyxisRC.com]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

Debra,

Ok thanks for getting back to me. I will plan on reviewing the document I sent earlier with respect to the percent crop treated.

Regards,

Janelle

JANELLE KAY



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
JANELLE@PYXISRC.COM

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Friday, February 21, 2020 12:08 PM
To: Janelle Kay <Janelle@PyxisRC.com>; Ann Tillman <Ann@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

Hi Janelle,

Unfortunately, I am not going to be able to provide any additional information to you this week. BEAD is invited to the meeting and you can look forward to hearing from them at that time. However, if this should change, I will be sure to let you know.

Otherwise, I look forward to the call on Monday.

Regards,
Debra

From: Janelle Kay <Janelle@PyxisRC.com>
Sent: Thursday, February 20, 2020 12:47 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Ann Tillman <Ann@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

Debra,

Thanks for the call-in information and we look forward to receiving more information from you and our all on Monday.

Regards,

Janelle

JANELLE KAY



4110 136TH ST CT NW
GIG HARBOR, WA 98332
T: (253) 853-7369
JANELLE@PYXISRC.COM

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, February 20, 2020 9:23 AM
To: Janelle Kay <Janelle@PyxisRC.com>; Ann Tillman <Ann@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

Hi Janelle,

I realized this morning that I had not yet provided you with the call in information for the meeting on Monday. The information for the conference line I will set up is as follows:

Phone: 1-202-991-0477
Code: 9621594

Additionally, I am still working to determine what information can be provided to in advance of the meeting Monday. I will update you on this as soon as I am able.

Regards,
Debra

From: Janelle Kay <Janelle@PyxisRC.com>
Sent: Friday, February 14, 2020 3:15 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Ann Tillman <Ann@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

Debra,

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Sent: Friday, February 14, 2020 4:06 AM
To: Janelle Kay <Janelle@PyxisRC.com>; Ann Tillman <Ann@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

Hi Janelle,

I will do that. For the call, I will have provided the team with the white paper that you sent earlier this week. Do you have any other specific agenda items or thoughts you would like for me to share that might ensure we are well prepared for this discussion?

Please let me know if you do.

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To: Rate, Debra <Rate.Debra@epa.gov>; Ann Tillman <Ann@PyxisRC.com>
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You can change that to a permanent hold; the date and time works for us!

-Janelle

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Sent: Thursday, February 13, 2020 1:53 PM
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Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

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Sent: Thursday, February 13, 2020 4:45 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Ann Tillman <Ann@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
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From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, February 13, 2020 1:04 PM
To: Janelle Kay <Janelle@PyxisRC.com>; Ann Tillman <Ann@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

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It appears that Monday February 24 from 11 – 12 pm may be available.

Does this day and time work for you and AgLogic?

If not, do you have some alternative times and dates in mind that you can provide to me? If you do, I will see what I am able to do to accommodate those times/dates.

Please let me know.

Thank you.

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Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

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Sent: Tuesday, January 28, 2020 12:24 PM
To: Janelle Kay <Janelle@PyxisRC.com>; Ann Tillman <Ann@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

Hi Janelle and Ann.

As follow up to our call last Thursday (1/23/20) and per our discussion regarding risk concerns for the proposed uses, I am reaching out to see if your client has made any decisions with regard to withdrawing these actions.

Please let me know.

Regards,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Adeeb, Shanta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DD827C964D6042EB87B3D98B2539BFB9-ADEEB, SHAN]
Sent: 2/18/2020 12:41:17 PM
To: Rate, Debra [Rate.Debra@epa.gov]
Subject: RE: Aldicarb: White paper for discussion on %CT assumptions for call on 2/24/20 (11 am - 12 pm)

Thanks Debra.

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, February 18, 2020 7:37 AM
To: Johnson, Hope <Johnson.Hope@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Jarboe, Stephen <Jarboe.Steve@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Waterworth, Rebecca <Waterworth.Rebecca@epa.gov>; Collantes, Margarita <Collantes.Margarita@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb: White paper for discussion on %CT assumptions for call on 2/24/20 (11 am - 12 pm)

Hi,

Attached is the white paper prepared by AgLogic for discussion on the call on Monday February 24 (11 am – 12 pm) concerning the %CT determined for the proposed use of aldicarb on oranges and grapefruit in Texas and Florida.

Please let me know if you have any questions or need any additional information as the meeting with AgLogic approaches.

Thank you!
Debra

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U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 2/18/2020 12:36:54 PM
To: Johnson, Hope [Johnson.Hope@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]; Jarboe, Stephen [Jarboe.Steve@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]; Waterworth, Rebekkah [Waterworth.Rebekkah@epa.gov]; Collantes, Margarita [Collantes.Margarita@epa.gov]; Becker, Jonathan [Becker.Jonathan@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: Aldicarb: White paper for discussion on %CT assumptions for call on 2/24/20 (11 am - 12 pm)
Attachments: 20200211 Determination of Percent Crop Treated for Oranges and Grapefruit_final.pdf

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Phone: 703-306-0309

Message

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Sent: 2/14/2020 8:32:29 PM
To: Janelle Kay [Janelle@PyxisRC.com]; Ann Tillman [Ann@PyxisRC.com]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

Thanks, Janelle. That sounds good. I will see what information from BEAD that I can provide to you in advance of the call, early next week.

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Phone: 703-306-0309

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To: Rate, Debra [Rate.Debra@epa.gov]; Ann Tillman [Ann@PyxisRC.com]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4
Attachments: 20200211 Determination of Percent Crop Treated for Oranges and Grapefruit_final.pdf

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JANELLE@PYXISRC.COM

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Wednesday, January 29, 2020 1:46 PM
To: Janelle Kay <Janelle@PyxisRC.com>; Ann Tillman <Ann@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

Hi Janelle,

Yes, we can provide the DEEM run input files. I spoke with the Health Effects scientist and he provided the input files that were used in this dietary assessment. These files are attached and described below:

1. 098301aFLTXS18.r08 Input file for DEEM version 3.16
2. 098301aFLTXS18.AC8 Results file for run
3. 098301aFLTXS18.TXT Input file in easy to read format.
4. 11 Residue Distribution Files needed for run.

To the replicate the results, the following parameters should be selected for the acute analysis:

- Divide by body wt.
- Under Foods/Food forms, select Eating occasion
 - Residue reversal: 2 hours

Monte Carlo Analysis:

- 1000 iterations
- Seed: 8
- Hold daily residue amount constant

PCT values for orange, orange juice, grapefruit, and grapefruit juice were 65%, 85%, 90% and 90%, respectively, as is reflected in the RDFs. These are the agency determined values for PCT as described on the phone call last week. The other parameters were the same parameters used in the most recent agency aldicarb dietary assessment (Nov. 2017).

Please let us know as soon as you are able about the timing of the meeting so that we can check availability and make sure that the appropriate individuals are available for the call.

Regards,
Debra

From: Janelle Kay <Janelle@PyxisRC.com>
Sent: Wednesday, January 29, 2020 12:08 AM
To: Rate, Debra <Rate.Debra@epa.gov>; Ann Tillman <Ann@PyxisRC.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

Debra,

I am currently traveling and won't be back until next week, but I can confirm that AgLogic does not intend on withdrawing at this time. They are discussing internally and would like to have a follow-up call with EPA soon (possibly next week?). In the meantime, would you be able to send the DEEM results? I'll be in touch next week after I get back to the office.

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Hi Janelle and Ann.

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Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Janelle Kay [Janelle@PyxisRC.com]
Sent: 2/4/2020 5:24:45 AM
To: Rate, Debra [Rate.Debra@epa.gov]; Ann Tillman [Ann@PyxisRC.com]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4

Thanks Debra,

I was out all last week, but we will take a look at these and be in touch.

Regards,

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Phone: 703-306-0309

Message

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To: Janelle Kay [Janelle@PyxisRC.com]; Ann Tillman [Ann@PyxisRC.com]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Follow-up to call 1/23/20 - Aldicarb New Uses: EPA Reg. Nos. 87895-2 and 87895-4
Attachments: 098301aFLTXS18.AC8; 098301aFLTXS18.TXT; RDF 1 Potato_Sweet.rdf; RDF 2 Potato_Sweet_BF.rdf; RDF 3 Orange_domestic use FL TX.rdf; RDF 4 Orange_Juice_85 PCT FL TX.rdf; RDF 5 Lemon 10 PCT.rdf; RDF 11 Pecan_FTD_58Perc Import.rdf; RDF 10 Grapefruit juice 90 PCT FL TX.rdf; RDF 9 Grapefruit 90PCT FL TX.rdf; RDF 8 Lime Juice 100PCT based on Orange Juice PDP.rdf; RDF 7 Lime 100PCT based on Orange PDP.rdf; RDF 6 Lemon_Juice_10 PCT.rdf; 098301aFLTXS18.r08

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Phone: 703-306-0309

US EPA

Ver. 3.18, 03-08-d

DEEM-FCID ACUTE Analysis for ALDICARB

NHANES 2003-2008 2-Day

Residue file: 098301aFLTXS18.r08

Adjustment factor #2 NOT used.

Analysis Date: 11-25-2019/13:57:47 Residue file dated: 11-25-2019/13:28:42

RAC/FF intake reported by eating occasion

Reversal analysis used with half life = 2 hr(s)

MC iterations = 1000; MC list in residue file; MC seed = 8; RNG = MS VB

MC residues held constant for each RAC/FF intake on same day/iteration

Run Comment: "Acute Dietary Assessment FL TX orange grapefruit Nov 2019 SLUA"

=====

Summary calculations--per capita:

95th Percentile		99th Percentile		99.9th Percentile	
Exposure	% aRfD	Exposure	% aRfD	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
Total US Population:					
0.000027	10.00	0.000060	22.04	0.000144	53.46
All Infants:					
0.000019	7.07	0.000055	20.35	0.000129	47.91
Children 1-2:					
0.000086	31.69	0.000173	64.19	0.000318	117.67
Children 3-5:					
0.000070	26.02	0.000133	49.42	0.000219	81.15
Children 6-12:					
0.000038	14.09	0.000070	26.08	0.000160	59.14
Youth 13-19:					
0.000028	10.37	0.000048	17.87	0.000080	29.75
Adults 20-49:					
0.000023	8.41	0.000042	15.56	0.000087	32.15
Adults 50-99:					
0.000021	7.83	0.000040	14.80	0.000076	28.28
Female 13-49:					
0.000024	8.74	0.000043	16.05	0.000074	27.32

US EPA

Ver. 3.18, 03-08-d

DEEM-FCID ACUTE Analysis for ALDICARB

NHANES 2003-2008 2-Day

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Run Comment: "Acute Dietary Assessment FL TX orange grapefruit Nov 2019 SLUA"

Summary calculations--users:

95th Percentile		99th Percentile		99.9th Percentile	
Exposure	% aRfD	Exposure	% aRfD	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
Total US Population:					
0.000027	10.02	0.000060	22.07	0.000144	53.50
All Infants:					
0.000022	8.22	0.000056	20.89	0.000134	49.62
Children 1-2:					
0.000086	31.70	0.000173	64.21	0.000318	117.68
Children 3-5:					
0.000070	26.02	0.000133	49.42	0.000219	81.15
Children 6-12:					
0.000038	14.09	0.000070	26.09	0.000160	59.15
Youth 13-19:					
0.000028	10.38	0.000048	17.89	0.000080	29.76
Adults 20-49:					
0.000023	8.43	0.000042	15.57	0.000087	32.17
Adults 50-99:					
0.000021	7.83	0.000040	14.80	0.000076	28.28
Female 13-49:					
0.000024	8.76	0.000043	16.07	0.000074	27.37

US EPA Ver. 3.18, 03-08-d
 DEEM-FCID ACUTE Analysis for ALDICARB NHANES 2003-2008 2-Day
 Residue file: 098301aFLTXS18.r08 Adjustment factor #2 NOT used.
 Analysis Date: 11-25-2019/13:57:47 Residue file dated: 11-25-2019/13:28:42
 Acute Reference Dose (aRfD) = 0.000270 mg/kg body-wt/day
 RAC/FF intake reported by eating occasion
 Reversal analysis used with half life = 2 hr(s)
 MC iterations = 1000; MC list in residue file; MC seed = 8; RNG = MS VB
 MC residues held constant for each RAC/FF intake on same day/iteration
 Run Comment: "Acute Dietary Assessment FL TX orange grapefruit Nov 2019 SLUA"

=====

Total US Population		Daily Exposure Analysis /a	
-----		(mg/kg body-weight/day)	
per Capita	per User		
-----	-----		
Mean	0.000005	0.000005	
Standard Deviation	0.000013	0.000013	
Percent of aRfD	1.91	1.92	

Percent of Person-Days that are User-Days = 99.64%

Estimated percentile of user-days falling below calculated exposure
 in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.01	90.00	0.000017	6.26
20.00	0.000000	0.02	95.00	0.000027	10.02

30.00	0.000000	0.05	97.50	0.000039	14.52
40.00	0.000000	0.13	99.00	0.000060	22.07
50.00	0.000001	0.25	99.50	0.000078	28.83
60.00	0.000001	0.41	99.75	0.000104	38.54
70.00	0.000002	0.67	99.90	0.000144	53.50
80.00	0.000005	1.83			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
10.00	0.000000	0.01	90.00	0.000017	6.24
20.00	0.000000	0.02	95.00	0.000027	10.00
30.00	0.000000	0.05	97.50	0.000039	14.49
40.00	0.000000	0.13	99.00	0.000060	22.04
50.00	0.000001	0.25	99.50	0.000078	28.77
60.00	0.000001	0.40	99.75	0.000104	38.50
70.00	0.000002	0.67	99.90	0.000144	53.46
80.00	0.000005	1.80			

a/ Analysis based on all two-day participant records in NHANES 2003-2008 2-Day survey.

1

US EPA Ver. 3.18, 03-08-d
DEEM-FCID ACUTE Analysis for ALDICARB NHANES 2003-2008 2-Day
Residue file: 098301aFLTXS18.r08 Adjustment factor #2 NOT used.
Analysis Date: 11-25-2019/13:57:47 Residue file dated: 11-25-2019/13:28:42
Acute Reference Dose (aRfD) = 0.000270 mg/kg body-wt/day
RAC/FF intake reported by eating occasion
Reversal analysis used with half life = 2 hr(s)
MC iterations = 1000; MC list in residue file; MC seed = 8; RNG = MS VB
MC residues held constant for each RAC/FF intake on same day/iteration
Run Comment: "Acute Dietary Assessment FL TX orange grapefruit Nov 2019 SLUA"

All Infants Daily Exposure Analysis

ED_005427A_00001403-00004

----- (mg/kg body-weight/day)

per Capita per User

Mean	0.000003	0.000003
Standard Deviation	0.000011	0.000012
Percent of aRfD	1.05	1.18

Percent of Person-Days that are User-Days = 89.21%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.00	90.00	0.000005	1.99
20.00	0.000000	0.01	95.00	0.000022	8.22
30.00	0.000000	0.01	97.50	0.000041	15.15
40.00	0.000000	0.02	99.00	0.000056	20.89
50.00	0.000000	0.02	99.50	0.000081	30.17
60.00	0.000000	0.02	99.75	0.000112	41.48
70.00	0.000000	0.06	99.90	0.000134	49.62
80.00	0.000001	0.19			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.00	90.00	0.000005	1.68
20.00	0.000000	0.00	95.00	0.000019	7.07
30.00	0.000000	0.01	97.50	0.000035	13.12
40.00	0.000000	0.01	99.00	0.000055	20.35
50.00	0.000000	0.02	99.50	0.000077	28.38
60.00	0.000000	0.02	99.75	0.000093	34.51
70.00	0.000000	0.05	99.90	0.000129	47.91
80.00	0.000000	0.14			

US EPA

Ver. 3.18, 03-08-d

DEEM-FCID ACUTE Analysis for ALDICARB

NHANES 2003-2008 2-Day

Residue file: 098301aFLTXS18.r08

Adjustment factor #2 NOT used.

Analysis Date: 11-25-2019/13:57:47 Residue file dated: 11-25-2019/13:28:42

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RAC/FF intake reported by eating occasion

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MC iterations = 1000; MC list in residue file; MC seed = 8; RNG = MS VB

MC residues held constant for each RAC/FF intake on same day/iteration

Run Comment: "Acute Dietary Assessment FL TX orange grapefruit Nov 2019 SLUA"

Children 1-2 Daily Exposure Analysis

(mg/kg body-weight/day)

per Capita per User

Mean 0.000016 0.000016

Standard Deviation 0.000038 0.000038

Percent of aRfD 6.08 6.09

Percent of Person-Days that are User-Days = 99.80%

Estimated percentile of user-days falling below calculated exposure

in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.03	90.00	0.000059	22.01
20.00	0.000000	0.06	95.00	0.000086	31.70
30.00	0.000000	0.08	97.50	0.000118	43.87
40.00	0.000000	0.17	99.00	0.000173	64.21
50.00	0.000001	0.45	99.50	0.000207	76.83
60.00	0.000003	1.06	99.75	0.000241	89.27
70.00	0.000006	2.40	99.90	0.000318	117.68
80.00	0.000022	8.02			

Estimated percentile of per-capita days falling below calculated exposure

in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
------------	----------	--------	------------	----------	--------

10.00	0.000000	0.03	90.00	0.000059	21.78
20.00	0.000000	0.05	95.00	0.000086	31.69
30.00	0.000000	0.08	97.50	0.000118	43.86
40.00	0.000000	0.17	99.00	0.000173	64.19
50.00	0.000001	0.45	99.50	0.000207	76.80
60.00	0.000003	1.05	99.75	0.000241	89.26
70.00	0.000006	2.39	99.90	0.000318	117.67
80.00	0.000022	8.00			

3

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 =====

Children 3-5 Daily Exposure Analysis

 (mg/kg body-weight/day)

per Capita per User

Mean	0.000014	0.000014
Standard Deviation	0.000029	0.000029
Percent of aRfD	5.18	5.18

Percent of Person-Days that are User-Days = 99.98%

Estimated percentile of user-days falling below calculated exposure
 in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.03	90.00	0.000047	17.40
20.00	0.000000	0.06	95.00	0.000070	26.02
30.00	0.000000	0.10	97.50	0.000094	34.80
40.00	0.000001	0.20	99.00	0.000133	49.42
50.00	0.000001	0.51	99.50	0.000157	58.22
60.00	0.000002	0.92	99.75	0.000171	63.27
70.00	0.000005	1.93	99.90	0.000219	81.15
80.00	0.000028	10.20			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.03	90.00	0.000047	17.40
20.00	0.000000	0.06	95.00	0.000070	26.02
30.00	0.000000	0.10	97.50	0.000094	34.80
40.00	0.000001	0.20	99.00	0.000133	49.42
50.00	0.000001	0.51	99.50	0.000157	58.22
60.00	0.000002	0.92	99.75	0.000171	63.27
70.00	0.000005	1.93	99.90	0.000219	81.15
80.00	0.000028	10.20			

4

US EPA Ver. 3.18, 03-08-d
DEEM-FCID ACUTE Analysis for ALDICARB NHANES 2003-2008 2-Day
Residue file: 098301aFLTXS18.r08 Adjustment factor #2 NOT used.
Analysis Date: 11-25-2019/13:57:47 Residue file dated: 11-25-2019/13:28:42
Acute Reference Dose (aRfD) = 0.000270 mg/kg body-wt/day
RAC/FF intake reported by eating occasion
Reversal analysis used with half life = 2 hr(s)
MC iterations = 1000; MC list in residue file; MC seed = 8; RNG = MS VB
MC residues held constant for each RAC/FF intake on same day/iteration

Run Comment: "Acute Dietary Assessment FL TX orange grapefruit Nov 2019 SLUA"

Children 6-12 Daily Exposure Analysis
----- (mg/kg body-weight/day)

per Capita	per User
------------	----------

Mean	0.000007	0.000007
Standard Deviation	0.000016	0.000016
Percent of aRfD	2.49	2.49

Percent of Person-Days that are User-Days = 99.94%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.01	90.00	0.000025	9.08
20.00	0.000000	0.03	95.00	0.000038	14.09
30.00	0.000000	0.05	97.50	0.000052	19.40
40.00	0.000000	0.07	99.00	0.000070	26.09
50.00	0.000000	0.15	99.50	0.000091	33.75
60.00	0.000001	0.33	99.75	0.000108	40.12
70.00	0.000002	0.72	99.90	0.000160	59.15
80.00	0.000006	2.14			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.01	90.00	0.000024	9.07
20.00	0.000000	0.03	95.00	0.000038	14.09
30.00	0.000000	0.05	97.50	0.000052	19.39
40.00	0.000000	0.07	99.00	0.000070	26.08
50.00	0.000000	0.15	99.50	0.000091	33.75
60.00	0.000001	0.32	99.75	0.000108	40.11
70.00	0.000002	0.72	99.90	0.000160	59.14
80.00	0.000006	2.13			

US EPA Ver. 3.18, 03-08-d
 DEEM-FCID ACUTE Analysis for ALDICARB NHANES 2003-2008 2-Day
 Residue file: 098301aFLTXS18.r08 Adjustment factor #2 NOT used.
 Analysis Date: 11-25-2019/13:57:47 Residue file dated: 11-25-2019/13:28:42
 Acute Reference Dose (aRfD) = 0.000270 mg/kg body-wt/day
 RAC/FF intake reported by eating occasion
 Reversal analysis used with half life = 2 hr(s)
 MC iterations = 1000; MC list in residue file; MC seed = 8; RNG = MS VB
 MC residues held constant for each RAC/FF intake on same day/iteration
 Run Comment: "Acute Dietary Assessment FL TX orange grapefruit Nov 2019 SLUA"

Youth 13-19 Daily Exposure Analysis

 (mg/kg body-weight/day)

per Capita per User

Mean	0.000004	0.000004
Standard Deviation	0.000010	0.000010
Percent of aRfD	1.56	1.57

Percent of Person-Days that are User-Days = 99.61%

Estimated percentile of user-days falling below calculated exposure
 in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.01	90.00	0.000018	6.53
20.00	0.000000	0.01	95.00	0.000028	10.38
30.00	0.000000	0.02	97.50	0.000036	13.34
40.00	0.000000	0.03	99.00	0.000048	17.89
50.00	0.000000	0.06	99.50	0.000055	20.39
60.00	0.000000	0.12	99.75	0.000065	24.02
70.00	0.000001	0.27	99.90	0.000080	29.76
80.00	0.000002	0.87			

Estimated percentile of per-capita days falling below calculated exposure

in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.01	90.00	0.000018	6.49
20.00	0.000000	0.01	95.00	0.000028	10.37
30.00	0.000000	0.02	97.50	0.000036	13.33
40.00	0.000000	0.03	99.00	0.000048	17.87
50.00	0.000000	0.06	99.50	0.000055	20.33
60.00	0.000000	0.12	99.75	0.000065	24.02
70.00	0.000001	0.27	99.90	0.000080	29.75
80.00	0.000002	0.87			

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US EPA

Ver. 3.18, 03-08-d

DEEM-FCID ACUTE Analysis for ALDICARB

NHANES 2003-2008 2-Day

Residue file: 098301aFLTXS18.r08

Adjustment factor #2 NOT used.

Analysis Date: 11-25-2019/13:57:47 Residue file dated: 11-25-2019/13:28:42

Acute Reference Dose (aRfD) = 0.000270 mg/kg body-wt/day

RAC/FF intake reported by eating occasion

Reversal analysis used with half life = 2 hr(s)

MC iterations = 1000; MC list in residue file; MC seed = 8; RNG = MS VB

MC residues held constant for each RAC/FF intake on same day/iteration

Run Comment: "Acute Dietary Assessment FL TX orange grapefruit Nov 2019 SLUA"

Adults 20-49

Daily Exposure Analysis

(mg/kg body-weight/day)

per Capita per User

Mean 0.000004 0.000004

Standard Deviation 0.000009 0.000009

Percent of aRfD 1.44 1.44

Percent of Person-Days that are User-Days = 99.70%

Estimated percentile of user-days falling below calculated exposure
in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.01	90.00	0.000015	5.41
20.00	0.000000	0.02	95.00	0.000023	8.43
30.00	0.000000	0.04	97.50	0.000030	11.06
40.00	0.000000	0.10	99.00	0.000042	15.57
50.00	0.000001	0.20	99.50	0.000051	18.92
60.00	0.000001	0.34	99.75	0.000063	23.38
70.00	0.000001	0.55	99.90	0.000087	32.17
80.00	0.000003	1.06			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.01	90.00	0.000015	5.39
20.00	0.000000	0.02	95.00	0.000023	8.41
30.00	0.000000	0.04	97.50	0.000030	11.05
40.00	0.000000	0.10	99.00	0.000042	15.56
50.00	0.000001	0.20	99.50	0.000051	18.90
60.00	0.000001	0.34	99.75	0.000063	23.37
70.00	0.000001	0.55	99.90	0.000087	32.15
80.00	0.000003	1.05			

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US EPA

Ver. 3.18, 03-08-d

DEEM-FCID ACUTE Analysis for ALDICARB

NHANES 2003-2008 2-Day

Residue file: 098301aFLTXS18.r08

Adjustment factor #2 NOT used.

Analysis Date: 11-25-2019/13:57:47 Residue file dated: 11-25-2019/13:28:42

Acute Reference Dose (aRfD) = 0.000270 mg/kg body-wt/day

RAC/FF intake reported by eating occasion

Reversal analysis used with half life = 2 hr(s)

US EPA Ver. 3.18, 03-08-d
 DEEM-FCID ACUTE Analysis for ALDICARB NHANES 2003-2008 2-Day
 Residue file: 098301aFLTXS18.r08 Adjustment factor #2 NOT used.
 Analysis Date: 11-25-2019/13:57:47 Residue file dated: 11-25-2019/13:28:42
 Acute Reference Dose (aRfD) = 0.000270 mg/kg body-wt/day
 RAC/FF intake reported by eating occasion
 Reversal analysis used with half life = 2 hr(s)
 MC iterations = 1000; MC list in residue file; MC seed = 8; RNG = MS VB
 MC residues held constant for each RAC/FF intake on same day/iteration
 Run Comment: "Acute Dietary Assessment FL TX orange grapefruit Nov 2019 SLUA"

Female 13-49 Daily Exposure Analysis

 (mg/kg body-weight/day)

per Capita per User

Mean	0.000004	0.000004
Standard Deviation	0.000009	0.000009
Percent of aRfD	1.43	1.44

Percent of Person-Days that are User-Days = 99.68%

Estimated percentile of user-days falling below calculated exposure
 in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.01	90.00	0.000014	5.25
20.00	0.000000	0.02	95.00	0.000024	8.76
30.00	0.000000	0.03	97.50	0.000031	11.56
40.00	0.000000	0.08	99.00	0.000043	16.07
50.00	0.000000	0.17	99.50	0.000052	19.25
60.00	0.000001	0.30	99.75	0.000063	23.37
70.00	0.000001	0.50	99.90	0.000074	27.37
80.00	0.000003	1.00			

Estimated percentile of per-capita days falling below calculated exposure
in mg/kg body-wt/day with Percent of aRfD

Percentile	Exposure	% aRfD	Percentile	Exposure	% aRfD
-----	-----	-----	-----	-----	-----
10.00	0.000000	0.01	90.00	0.000014	5.23
20.00	0.000000	0.02	95.00	0.000024	8.74
30.00	0.000000	0.03	97.50	0.000031	11.55
40.00	0.000000	0.07	99.00	0.000043	16.05
50.00	0.000000	0.17	99.50	0.000052	19.24
60.00	0.000001	0.29	99.75	0.000063	23.35
70.00	0.000001	0.49	99.90	0.000074	27.32
80.00	0.000003	0.99			

Filename: C:\Users\wdonovan\Documents\DEEM Version 3.16\098301\098301aFLTXS18.r08

Chemical: Aldicarb

RfD(Chronic): 0 mg/kg bw/day NOEL(Chronic): 0 mg/kg bw/day

RfD(Acute): .00027 mg/kg bw/day NOEL(Acute): 0 mg/kg bw/day

Date created/last modified: 11-25-2019/10:48:31 Program ver. 3.16, 03-08-d

Comment: Acute Dietary Assessment FL TX orange grapefruit

RDL indices and parameters for Monte Carlo Analysis:

Index	Dist	Parameter #1	Param #2	Param #3	Comment
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#	Code
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1	6	RDF 1 Potato_Sweet.rdf			
2	6	RDF 2 Potato_Sweet_BF.rdf			
3	6	RDF 3 Orange_domestic use FL TX.rdf			
4	6	RDF 4 Orange_Juice_85 PCT FL TX.rdf			
5	6	RDF 5 Lemon 10 PCT.rdf			
6	6	RDF 6 Lemon_Juice_10 PCT.rdf			
7	6	RDF 7 Lime 100PCT based on Orange PDP.rdf			
8	6	RDF 8 Lime Juice 100PCT based on Orange Juice PDP.rdf			
9	6	RDF 9 Grapefruit 90PCT FL TX.rdf			
10	6	RDF 10 Grapefruit juice 90 PCT FL TX.rdf			
11	6	RDF 11 Pecan_FTD_58Perc Import.rdf			

EPA Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Factors #1	#2	RDLComment Pntr
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0103296000	1C	Potato, chips	0.000232	0.620	1.000	
0103297000	1C	Potato, dry (granules/ flakes)	0.000232	6.500	1.000	
0103297001	1C	Potato, dry (granules/ flakes)-b	0.000232	6.500	1.000	
0103298000	1C	Potato, flour	0.000232	6.500	1.000	
0103298001	1C	Potato, flour-babyfood	0.000232	6.500	1.000	
0103366000	1CD	Sweet potato				
210-Cooked; Fresh or N/S; Cook Meth N/S						
1.000000	1.000	1.000	1			
211-Cooked; Fresh or N/S; Baked						
1.000000	1.000	1.000	1			
212-Cooked; Fresh or N/S; Boiled						
1.000000	0.500	1.000	1			
213-Cooked; Fresh or N/S; Fried						
1.000000	0.620	1.000	1			

215-Cooked; Fresh or N/S; Boiled/baked

1.000000 1.000 1.000 1

240-Cooked; Canned; Cook Meth N/S

1.000000 0.500 1.000 1

242-Cooked; Canned; Boiled 1.000000 0.500 1.000 1

0103366001 1CD Sweet potato-babyfood

211-Cooked; Fresh or N/S; Baked

1.000000 1.000 1.000 2

240-Cooked; Canned; Cook Meth N/S

1.000000 0.500 1.000 2

0600347000 6 Soybean, seed 0.000214 1.000 1.000

0600349000 6 Soybean, soy milk 0.000214 1.000 1.000

0600349001 6 Soybean, soy milk-babyfood or in 0.000214 1.000 1.000

0600350000 6 Soybean, oil 0.000214 0.300 1.000

0600350001 6 Soybean, oil-babyfood 0.000214 0.300 1.000

0603030000 6C Bean, black, seed 0.000214 0.050 1.000

0603032000 6C Bean, broad, seed 0.000214 0.050 1.000

0603034000 6C Bean, cowpea, seed 0.000214 0.050 1.000

0603035000 6C Bean, great northern, seed 0.000214 0.050 1.000

0603036000 6C Bean, kidney, seed 0.000214 0.050 1.000

0603038000 6C Bean, lima, seed 0.000214 0.050 1.000

0603039000 6C Bean, mung, seed 0.000214 0.050 1.000

0603040000 6C Bean, navy, seed 0.000214 0.050 1.000

0603041000 6C Bean, pink, seed 0.000214 0.050 1.000

0603042000 6C Bean, pinto, seed 0.000214 0.050 1.000

0603098000 6C Chickpea, seed 0.000214 0.050 1.000

0603098001 6C Chickpea, seed-babyfood 0.000214 0.050 1.000

0603099000 6C Chickpea, flour 0.000214 0.050 1.000

0603182000 6C Guar, seed 0.000214 0.050 1.000

0603182001 6C Guar, seed-babyfood 0.000214 0.050 1.000

0603348000 6C Soybean, flour 0.000214 1.000 1.000

0603348001 6C Soybean, flour-babyfood 0.000214 1.000 1.000

1001240000 10A Orange 1.000000 1.000 1.000 3

1001241000 10A Orange, juice 1.000000 1.000 1.000 4

1001241001 10A Orange, juice-babyfood 1.000000 1.000 1.000 4

1001242000 10A Orange, peel 1.000000 1.000 1.000 3

1002199000 10B Lemon 1.000000 1.000 1.000 5

1002200000 10B Lemon, juice 1.000000 1.000 1.000 6

1002200001 10B Lemon, juice-babyfood 1.000000 1.000 1.000 6

1002201000	10B	Lemon, peel	1.000000	1.000	1.000	5
1002206000	10B	Lime	1.000000	1.000	1.000	7
1002207000	10B	Lime, juice	1.000000	1.000	1.000	8
1002207001	10B	Lime, juice-babyfood	1.000000	1.000	1.000	8
1003180000	10C	Grapefruit	1.000000	1.000	1.000	9
1003181000	10C	Grapefruit, juice	1.000000	1.000	1.000	10
1400269000	14	Pecan	1.000000	1.000	1.000	11
2003128000	20C	Cottonseed, oil	0.015900	0.100	1.000	
2003128001	20C	Cottonseed, oil-babyfood	0.015900	0.100	1.000	
9500115000	O	Coffee, roasted bean	0.008550	1.000	1.000	
9500116000	O	Coffee, instant	0.008550	1.000	1.000	
9500263000	O	Peanut	0.002115	1.000	1.000	
9500264000	O	Peanut, butter	0.002115	1.200	1.000	
9500265000	O	Peanut, oil	0.002115	0.180	1.000	

'Aldicarb, Created by SAS Program: CreateRDF_031714, 03NOV15

'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Aldicarb, RDF Filename=Potato_Sweet.rdf

'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD2

'PDP Data: SWFR (2008,2009,2010), Total Samples=1476, Total Detects=5, Total LODs=1471,
Total Zeros=0

'MaxPCT=34, Avg Residue (Detects)=0.038920, Avg Residue (TOTALS)=0.0017, Avg Residue
(Blended, PCT=100)=0.010967, Avg HLOD (NonDetects)=0.0109

TOTALZ=974

TOTALLOD=497

LODRES=0.0109

0.07784

0.06594

0.02126

0.01478

0.01478

'Aldicarb, Created by SAS Program: CreateRDF_031714, 03NOV15
'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Aldicarb, RDF Filename=Potato_Sweet_BF.rdf
'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD2
'PDP Data: ISGJ,ISPC,ISSE (2010,2011), Total Samples=776, Total Detects=0, Total
LODs=776, Total Zeros=0
'MaxPCT=34, Avg Residue (Detects)=., Avg Residue (TOTALS)=0.0012, Avg Residue (Blended,
PCT=100)=0.008340, Avg HLOD (NonDetects)=0.0083
TOTALZ=512
TOTALLOD=264
LODRES=0.0083

'Aldicarb, Created by SAS Program: CreateRDF_031714, 03NOV15 (Modified on 11/15/2015 to include 8% of Import Oranges)

'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Aldicarb, RDF Filename=Orange.rdf

'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD2

'PDP Data: OGFR (2009,2010), Total Samples=1488, Total Detects=4, Total LODs=963, Total Zeros=521

'65% Crop Treated, Avg Residue (Detects)=0.018950, Avg Residue (TOTALS)=0.0131, Avg HLOD (NonDetects)=0.0131

TOTALZ=521

TOTALLOD=963

LODRES=0.0131

0.02126

0.02034

0.01942

0.01478

'Aldicarb, Created by SAS Program: CreateRDF_031714, 03NOV15, (modified on 11/25/2015 to include 8% of imports)

'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Aldicarb, RDF Filename=Orange_Juice.rdf

'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD2

'PDP Data: OJCO,OJFZ,OJRE (2010,2011,2012), Total Samples=1106, Total Detects=5, Total LODs=935, Total Zeros=166

'85% Treated, Avg Residue (Detects)=0.006102, Avg Residue (TOTALS)=0.0042, Avg HLOD (NonDetects)=0.0042

TOTALZ=166

TOTALLOD=935

LODRES=0.0042

0.00647

0.00647

0.00647

0.00555

0.00555

'Aldicarb, Created by SAS Program: CreateRDF_031714, 03NOV15 (Modified on 11/15/2015 to include 10% of Import Lemon)

'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Aldicarb, RDF Filename=Orange.rdf

'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD2

'PDP Data: OGFR (2009,2010), Total Samples=1488, Total Detects=4, Total LODs=145, Total Zeros=1339

'10% Imports, Avg Residue (Detects)=0.018950, Avg Residue (TOTALS)=0.0131, Avg HLOD (NonDetects)=0.0131

TOTALZ=1339

TOTALLOD=145

LODRES=0.0131

0.02126

0.02034

0.01942

0.01478

'Pecan Aldicarb FTD 58% Imports (%Imports provided on 11/25/2015)

'Field Trial Residue Data [MRID No. 102123]; 22 treated samples

'Estimated Maximum %CT = 58% (Not on label; import use)

TOTALZ=16

TOTALLOD=0

LODRES=0.004

4,0.0043

2,0.0171

2,0.0256

2,0.0427

2,0.00855

0.0342

0.0684

0.0598

0.0513

0.0769

0.0940

0.0855

0.231

0.103

0.145

'Aldicarb, Created by SAS Program: CreateRDF_031714, 03NOV15, (modified on 11/25/2015 to include 2% of Grapefruit imports)

'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Aldicarb, RDF Filename=Orange_Juice.rdf

'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD2

'PDP Data: OJCO,OJFZ,OJRE (2010,2011,2012), Total Samples=1106, Total Detects=5, Total LODs=990, Total Zeros=111

'90% treated, Avg Residue (Detects)=0.006102, Avg Residue (TOTALS)=0.0042, Avg HLOD (NonDetects)=0.0042

TOTALZ=111

TOTALLOD=990

LODRES=0.0042

0.00647

0.00647

0.00647

0.00555

0.00555

'Aldicarb, Created by SAS Program: CreateRDF_031714, 03NOV15 (Modified on 11/15/2015 to include 2% of Import Lemon)

'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Aldicarb, RDF Filename=Orange.rdf

'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD2

'PDP Data: OGFR (2009,2010), Total Samples=1488, Total Detects=4, Total LODs=1335, Total Zeros=149

'90% Treated, Avg Residue (Detects)=0.018950, Avg Residue (TOTALS)=0.0131, Avg HLOD (NonDetects)=0.0131

TOTALZ=149

TOTALLOD=1335

LODRES=0.0131

0.02126

0.02034

0.01942

0.01478

'Aldicarb, Created by SAS Program: CreateRDF_031714, 03NOV15, (modified on 11/25/2015 to include 10% of imports)

'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Aldicarb, RDF Filename=Orange_Juice.rdf

'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD2

'PDP Data: OJCO,OJFZ,OJRE (2010,2011,2012), Total Samples=1106, Total Detects=5, Total LODs=106, Total Zeros=995

'10% Imports, Avg Residue (Detects)=0.006102, Avg Residue (TOTALS)=0.0042, Avg HLOD (NonDetects)=0.0042

TOTALZ=995

TOTALLOD=106

LODRES=0.0042

0.00647

0.00647

0.00647

0.00555

0.00555

"Aldicarb "

0

03-08-dMCNH2, 0.00027

NOEL, 0 0 0

11-25-2019/13:28:42

11

1 6 "RDF 1 Potato_Sweet.rdf", 0

2 6 "RDF 2 Potato_Sweet_BF.rdf", 0

3 6 "RDF 3 Orange_domestic use FL TX.rdf", 0

4 6 "RDF 4 Orange_Juice_85 PCT FL TX.rdf", 0

5 6 "RDF 5 Lemon 10 PCT.rdf", 0

6 6 "RDF 6 Lemon_Juice_10 PCT.rdf", 0

7 6 "RDF 7 Lime 100PCT based on Orange PDP.rdf", 0

8 6 "RDF 8 Lime Juice 100PCT based on Orange Juice PDP.rdf", 0

9 6 "RDF 9 Grapefruit 90PCT FL TX.rdf", 0

10 6 "RDF 10 Grapefruit juice 90 PCT FL TX.rdf", 0

11 6 "RDF 11 Pecan_FTD_58Perc Import.rdf", 0

-1 "Acute Dietary Assessment FL TX orange grapefruit "

999 1

45 "0603030000","6C", 0.000214 0 0 0.05 1 0 "Bean, black, seed", ""

47 "0603032000","6C", 0.000214 0 0 0.05 1 0 "Bean, broad, seed", ""

49 "0603034000","6C", 0.000214 0 0 0.05 1 0 "Bean, cowpea, seed", ""

50 "0603035000","6C", 0.000214 0 0 0.05 1 0 "Bean, great northern, seed", ""

51 "0603036000","6C", 0.000214 0 0 0.05 1 0 "Bean, kidney, seed", ""

53 "0603038000","6C", 0.000214 0 0 0.05 1 0 "Bean, lima, seed", ""

54 "0603039000","6C", 0.000214 0 0 0.05 1 0 "Bean, mung, seed", ""

55 "0603040000","6C", 0.000214 0 0 0.05 1 0 "Bean, navy, seed", ""

56 "0603041000","6C", 0.000214 0 0 0.05 1 0 "Bean, pink, seed", ""

57 "0603042000","6C", 0.000214 0 0 0.05 1 0 "Bean, pinto, seed", ""

133 "0603098000","6C", 0.000214 0 0 0.05 1 0 "Chickpea, seed", ""

134 "0603098001","6C", 0.000214 0 0 0.05 1 0 "Chickpea, seed-babyfood", ""

135 "0603099000","6C", 0.000214 0 0 0.05 1 0 "Chickpea, flour", ""

154 "9500115000","O", 0.00855 0 0 1 1 0 "Coffee, roasted bean", ""

155 "9500116000","O", 0.00855 0 0 1 1 0 "Coffee, instant", ""

175 "2003128000","20C", 0.0159 0 0 0.1 1 0 "Cottonseed, oil", ""

176 "2003128001","20C", 0.0159 0 0 0.1 1 0 "Cottonseed, oil-babyfood", ""

236 "1003180000","10C", 1 9 1 1 1 0 "Grapefruit", ""

237 "1003181000","10C", 1 10 1 1 1 0 "Grapefruit, juice", ""

238 "0603182000","6C", 0.000214 0 0 0.05 1 0 "Guar, seed", ""

239 "0603182001","6C", 0.000214 0 0 0.05 1 0 "Guar, seed-babyfood", ""
 259 "1002199000","10B", 1 5 1 1 1 0 "Lemon", ""
 260 "1002200000","10B", 1 6 1 1 1 0 "Lemon, juice", ""
 261 "1002200001","10B", 1 6 1 1 1 0 "Lemon, juice-babyfood", ""
 262 "1002201000","10B", 1 5 1 1 1 0 "Lemon, peel", ""
 267 "1002206000","10B", 1 7 1 1 1 0 "Lime", ""
 268 "1002207000","10B", 1 8 1 1 1 0 "Lime, juice", ""
 269 "1002207001","10B", 1 8 1 1 1 0 "Lime, juice-babyfood", ""
 312 "1001240000","10A", 1 3 1 1 1 0 "Orange", ""
 313 "1001241000","10A", 1 4 1 1 1 0 "Orange, juice", ""
 314 "1001241001","10A", 1 4 1 1 1 0 "Orange, juice-babyfood", ""
 315 "1001242000","10A", 1 3 1 1 1 0 "Orange, peel", ""
 347 "9500263000","O", 0.002115 0 0 1 1 0 "Peanut", ""
 348 "9500264000","O", 0.002115 0 0 1.2 1 0 "Peanut, butter", ""
 349 "9500265000","O", 0.002115 0 0 0.18 1 0 "Peanut, oil", ""
 355 "1400269000","14", 1 11 1 1 1 0 "Pecan", ""
 395 "0103296000","1C", 0.000232 0 0 0.62 1 0 "Potato, chips", ""
 396 "0103297000","1C", 0.000232 0 0 6.5 1 0 "Potato, dry (granules/ flakes)", ""
 397 "0103297001","1C", 0.000232 0 0 6.5 1 0 "Potato, dry (granules/ flakes)-
 babyfood", ""
 398 "0103298000","1C", 0.000232 0 0 6.5 1 0 "Potato, flour", ""
 399 "0103298001","1C", 0.000232 0 0 6.5 1 0 "Potato, flour-babyfood", ""
 463 "0600347000","6", 0.000214 0 0 1 1 0 "Soybean, seed", ""
 464 "0603348000","6C", 0.000214 0 0 1 1 0 "Soybean, flour", ""
 465 "0603348001","6C", 0.000214 0 0 1 1 0 "Soybean, flour-babyfood", ""
 466 "0600349000","6", 0.000214 0 0 1 1 0 "Soybean, soy milk", ""
 467 "0600349001","6", 0.000214 0 0 1 1 0 "Soybean, soy milk-babyfood or infant
 fo", ""
 468 "0600350000","6", 0.000214 0 0 0.3 1 0 "Soybean, oil", ""
 469 "0600350001","6", 0.000214 0 0 0.3 1 0 "Soybean, oil-babyfood", ""
 494 "0103366000","1CD", 1 1 1 1 1 7 "Sweet potato", ""
 210 "Cooked; Fresh or N/S; Cook Meth N/S", 1 1 1 1 1 ""
 211 "Cooked; Fresh or N/S; Baked", 1 1 1 1 1 ""
 212 "Cooked; Fresh or N/S; Boiled", 1 1 1 0.5 1 ""
 213 "Cooked; Fresh or N/S; Fried", 1 1 1 0.62 1 ""
 215 "Cooked; Fresh or N/S; Boiled/baked", 1 1 1 1 1 ""
 240 "Cooked; Canned; Cook Meth N/S", 1 1 1 0.5 1 ""
 242 "Cooked; Canned; Boiled", 1 1 1 0.5 1 ""
 495 "0103366001","1CD", 1 2 1 1 1 2 "Sweet potato-babyfood", ""
 211 "Cooked; Fresh or N/S; Baked", 1 2 1 1 1 ""

240 "Cooked; Canned; Cook Meth N/S", 1 2 1 0.5 1 ""

Message

From: Donovan, William [donovan.william@epa.gov]
Sent: 1/27/2020 3:20:19 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]
CC: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb - follow up to RD phone call with Pyxis
Attachments: 098301aFLTXS18.AC8; 098301aFLTXS18.TXT; RDF 1 Potato_Sweet.rdf; RDF 2 Potato_Sweet_BF.rdf; RDF 3 Orange_domestic use FL TX.rdf; RDF 4 Orange_Juice_85 PCT FL TX.rdf; RDF 5 Lemon 10 PCT.rdf; RDF 11 Pecan_FTD_58Perc Import.rdf; RDF 10 Grapefruit juice 90 PCT FL TX.rdf; RDF 9 Grapefruit 90PCT FL TX.rdf; RDF 8 Lime Juice 100PCT based on Orange Juice PDP.rdf; RDF 7 Lime 100PCT based on Orange PDP.rdf; RDF 6 Lemon_Juice_10 PCT.rdf; 098301aFLTXS18.r08

Hi Debra,

I am attaching the following files:

1. 098301aFLTXS18.r08 Input file for DEEM version 3.16
2. 098301aFLTXS18.AC8 Results file for run
3. 098301aFLTXS18.TXT Input file in easy to read format.
4. 11 Residue Distribution Files needed for run.

To obtain the results I did select the following parameters for the acute analysis:

- Divide by body wt.
- Under Foods/Foodforms, select Eating occasion
 - Residue reversal: 2 hours

Monte Carlo Analysis

- 1000 iterations
- Seed: 8
- Hold daily residue amount constant

Note that the PCT values for orange, orange juice, grapefruit, and grapefruit juice are 65, 85, 90, and 90%, respectively, as reflected in the RDFs. These PCT values were taken from the following: BEAD Memo, "Percent Crop Treated for New Use (PCTn): Aldicarb (098301) Use on Citrus". L. Hendrick et al, 10/16/2019 Product Review Panel.

Other parameters used in the run, such as residue level, processing factors, and PCT for other crops are as used in the most recent aldicarb dietary memo: D444345, W. Donovan, 28-NOV-2017.

Please let me know if you have any questions about this. Thanks,

Will

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Friday, January 24, 2020 1:47 PM
To: Donovan, William <donovan.william@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - follow up to RD phone call with Pyxis

Monday would be wonderful if that works for you. Thank you! Debra

From: Donovan, William <donovan.william@epa.gov>
Sent: Friday, January 24, 2020 10:49 AM
To: Metzger, Michael <Metzger.Michael@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>

Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: RE: Aldicarb - follow up to RD phone call with Pyxis

Hi Debra,

Is Monday ok? Would like to double check my files and organize them so they can follow what I did. Thanks,

Will

From: Metzger, Michael <Metzger.Michael@epa.gov>

Sent: Friday, January 24, 2020 10:24 AM

To: Rate, Debra <Rate.Debra@epa.gov>; Donovan, William <donovan.william@epa.gov>

Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: RE: Aldicarb - follow up to RD phone call with Pyxis

Yup – We can give them the files. Thanks. Mike

From: Rate, Debra <Rate.Debra@epa.gov>

Sent: Friday, January 24, 2020 10:19 AM

To: Metzger, Michael <Metzger.Michael@epa.gov>; Donovan, William <donovan.william@epa.gov>

Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: Aldicarb - follow up to RD phone call with Pyxis

Hi Mike, Will,

Marion, Shanta and I spoke with Pyxis yesterday afternoon (1/23/20) about the pending Aldicarb submissions and where the agency currently stands with risk concerns. They wanted to know if we could provide them with the DEEM inputs that were used to arrive at the 117% aPAD (children 1-2 yrs). They want provide that to their client (AgLogic) so that they can recreate the DEEM run.

Since this wasn't a formal assessment, is this something that HED would be comfortable providing to Pyxis? Please let us know.

Thanks,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Aubee, Catherine [Aubee.Catherine@epa.gov]
Sent: 1/21/2020 10:48:48 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Goodis, Michael [Goodis.Michael@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]
Subject: Re: Aldicarb Memo

Seeing that Mike already sent this up. I'll follow up with you offline out of curiosity, so I can better understand the difference in **Ex. 5 Deliberative Process (DP)**

Best,
Catherine

On Jan 21, 2020, at 5:44 PM, Aubee.Catherine@epa.gov wrote:

Thanks for letting me sit in on your discussion today. Now that I've read this again -

I suggest adding a brief explanation of why **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

I know you are trying to move this forward; thanks for considering this late comment.

Best,
Catherine

On Jan 21, 2020, at 5:01 PM, Johnson, Marion <Johnson.Marion@epa.gov> wrote:

Mike,

Ex. 5 Deliberative Process (DP)
EX. 5 Deliberative Process (DP)

Regards

J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
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Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Tuesday, January 21, 2020 7:07 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>
Subject: RE: Aldicarb Memo

Hi Marion

I made some further edits to the paper and a couple of comments based on my conversation with Rick about it.

Ex. 5 Deliberative Process (DP)

Please look it over and make sure I captured things correctly. I would like to send to him today please.

Let me know if you have any questions. Thanks

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Wednesday, January 15, 2020 11:51 AM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>
Subject: RE: Aldicarb Memo
Importance: High

Mike,

I think we've addressed the latest round of concerns, so take a look at the first attachment and let us know if there are any remaining concerns/questions. Of course, the second attachment contains previous comments for your comparison and record.

Marion J.

Marion J. Johnson, Jr.
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Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Sunday, January 12, 2020 4:23 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

Thanks everyone – attached are some edits/comments. Feel free to change any edits that I made that are not correct. Let me know if you have questions.

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Thursday, January 09, 2020 5:16 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo
Importance: High

Mike, et.al.:

Please disregard the first document below, as I failed to “delete all comments”. I’m attaching the final edited document, as required. Many thanks!

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
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Visit: <http://www.epa.gov/pesticides>

From: Johnson, Marion
Sent: Thursday, January 9, 2020 12:14 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

Mike,

Attached is the most updated aldicarb "one pager" which incorporates responses to your questions/comments. The second document contains your original comments and has been provided for comparison purposes only, as track changes were

Ex. 5 Deliberative Process (DP)

Marion J.

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Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Monday, December 30, 2019 2:57 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

Ex. 5 Deliberative Process (DP)

Let me know if you have any questions.

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Monday, December 23, 2019 11:45 AM
To: Davis, Donna <Davis.Donna@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

Donna, et. al.:

Thanks for pulling this together.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Otherwise,

I'm fine with this version but let me know if you have additional thoughts.

Best regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
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Office of Pesticide Programs
Registration Division
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Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Davis, Donna <Davis.Donna@epa.gov>
Sent: Friday, December 20, 2019 10:41 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

I took a run at developing a document that I think is the right level of detail and tone for briefing the AA.

Mike/Dan,
Please advise if this is the right level of detail to brief up.

Marion/Debra,

If Mike/Dan concur this works, I suspect it needs a little more work and a few tweaks, but can you take the lead in finalizing?

Donna

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Thursday, December 19, 2019 1:27 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Davis, Donna <Davis.Donna@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: FW: Aldicarb Memo
Importance: High

Mike,

Ex. 5 Deliberative Process (DP)

Regards

Marion

J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
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(703) 305-6788 (tel)
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Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, December 19, 2019 12:51 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb memo - corrected

Marion,

I made the corrections to the memo that you dropped off and we discussed in this version.

Thanks,
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

<Aldicarb Citrus New Use Summary Papermj 1.21.20.docx>

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 1/21/2020 10:01:19 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]
Subject: RE: Aldicarb Memo
Attachments: Aldicarb Citrus New Use Summary Papermj 1.21.20.docx

Importance: High

Mike,

We've discussed and incorporated the last round of changes, as suggested.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Regards,

Marion J.

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Subject: RE: Aldicarb Memo

Hi Marion

Ex. 5 Deliberative Process (DP)

Please look it over and make sure I captured things correctly. I would like to send to him today please.
Let me know if you have any questions. Thanks

Michael L. Goodis, P.E.

ED_005427A_00001443-00001

Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

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Sent: Wednesday, January 15, 2020 11:51 AM
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Subject: RE: Aldicarb Memo
Importance: High

Mike,

I think we've addressed the latest round of concerns, so take a look at the first attachment and let us know if there are any remaining concerns/questions. Of course, the second attachment contains previous comments for your comparison and record.

Marion J.

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Subject: RE: Aldicarb Memo

Thanks everyone – attached are some edits/comments. Feel free to change any edits that I made that are not correct. Let me know if you have questions.

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Office of Pesticide Programs (OPP)

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Subject: RE: Aldicarb Memo

Importance: High

Mike, et.al.:

Please disregard the first document below, as I failed to "delete all comments". I'm attaching the final edited document, as required. Many thanks!

Marion J.

Marion J. Johnson, Jr.
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From: Johnson, Marion

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To: Goodis, Michael <Goodis.Michael@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>

Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>

Subject: RE: Aldicarb Memo

Mike,

Attached is the most updated aldicarb "one pager" which incorporates responses to your questions/comments. The second document contains your original comments and has been provided for comparison purposes only, as track changes were becoming too distracting. Thus, we think that we've addressed your thoughts, while still keeping the document tailored and structured to the AA's needs. However, let us know, if you have further questions.

Marion J.

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Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra

<Rate.Debra@epa.gov>

Subject: RE: Aldicarb Memo

Ex. 5 Deliberative Process (DP)

Michael L. Goodis, P.E.

Director, Registration Division (RD)

Office of Pesticide Programs (OPP)

Phone 703-308-8157

Room S7623

From: Johnson, Marion <Johnson.Marion@epa.gov>

Sent: Monday, December 23, 2019 11:45 AM

To: Davis, Donna <Davis.Donna@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>

Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>

Subject: RE: Aldicarb Memo

Donna, et. al.:

Thanks for pulling this together.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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Best regards,

Marion J.

Marion J. Johnson, Jr.

Chief, Invertebrate-Vertebrate Branch 2

U.S. Environmental Protection Agency

Office of Pesticide Programs

Registration Division

(703) 305-6788 (tel)

(703) 308-0029 (fax)

Johnson.marion@epa.gov

Visit: <http://www.epa.gov/pesticides>

From: Davis, Donna <Davis.Donna@epa.gov>

Sent: Friday, December 20, 2019 10:41 AM

To: Johnson, Marion <Johnson.Marion@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>

Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra

<Rate.Debra@epa.gov>

Subject: RE: Aldicarb Memo

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Cc: Davis, Donna <Davis.Donna@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>

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Importance: High

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To: Johnson, Marion <Johnson.Marion@epa.gov>

Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: Aldicarb memo - corrected

Marion,

I made the corrections to the memo that you dropped off and we discussed in this version.

Thanks,

Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 1/21/2020 2:40:52 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]
Subject: RE: Aldicarb Memo

OK. I'll take a look and get back to you today.

MJJ

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From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Tuesday, January 21, 2020 7:07 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>
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Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

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Subject: RE: Aldicarb Memo
Attachments: Aldicarb Citrus New Use Summary Paperm 1.21.20.docx

Hi Marion

I made some further edits to the paper and a couple of comments based on my conversation with Rick about it.

Ex. 5 Deliberative Process (DP)

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Subject: FW: Aldicarb Memo
Importance: High

Mike,

Ex. 5 Deliberative Process (DP)

Therefore, let me know if you have further questions and/or suggestions. Not directly having briefed Alex before, we're simply trying to anticipate some of the questions that she may want to have addressed in such a session.

Regards,

Marion J.

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Thanks,
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Senior Regulatory Specialist
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Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Aldicarb Proposed Use on Citrus Issue Paper
January 14, 2020

Issue

AgLogic Chemical LLC (AgLogic) submitted an application for registration of new uses of aldicarb on oranges and grapefruit in Florida and Texas to control Asian citrus psyllid responsible for transmission of citrus greening. OPP met with the registrant to discuss the specific risk concerns with the proposed new uses for this active ingredient. Understanding the challenges, the registrant elected to make a submission on April 9, 2019. The PRIA due date for this action is July 15, 2020. Having completed review of the submission,

Ex. 5 Deliberative Process (DP)

OPP would like to alert the interested parties of our findings as soon as possible. There has been congressional interest on the progress and pending outcome of this application.

Regulatory History

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity, and to protect ground water.
- Aldicarb products are currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. There are no registered residential uses of aldicarb.
- In 2010, Bayer (the registrant at that time) voluntarily agreed to cancel the domestic aldicarb uses on citrus (and potatoes), due to the findings by EPA that the registered uses posed an unacceptable dietary risk, especially to infants and young children. However, the existing tolerances for citrus have been maintained to allow for treated imports. Further, the registrant adopted risk mitigation measures for the remaining uses to protect groundwater resources.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.

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Current Submission

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Benefits

- Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives.

Ex. 5 Deliberative Process (DP)

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- Use of aldicarb tends to produce higher yields.

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EPA's Current Evaluation of the Requested Use on Citrus in Florida and Texas

- OPP ~~technical experts~~ reviewed the white papers and analyses submitted by the registrant. The white papers suggested

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- OPP conducted a revised exposure assessment, which included the proposed domestic uses on oranges and grapefruit.

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Proposed Next Steps

Ex. 5 Deliberative Process (DP)

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 1/15/2020 4:51:18 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]
Subject: RE: Aldicarb Memo
Attachments: Aldicarb Citrus New Use Summary Paperm 1.14.20 dnrnj2 Comments (002).docx; Aldicarb Citrus New Use Summary Paper 1.13.20.docx

Importance: High

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From: Goodis, Michael <Goodis.Michael@epa.gov>

Sent: Monday, December 30, 2019 2:57 PM

To: Johnson, Marion <Johnson.Marion@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>

Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>

Subject: RE: Aldicarb Memo

Ex. 5 Deliberative Process (DP)

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Monday, December 23, 2019 11:45 AM
To: Davis, Donna <Davis.Donna@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

Donna, et. al.:

Thanks for pulling this together.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Otherwise, I'm fine

with this version but let me know if you have additional thoughts.

Best regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Davis, Donna <Davis.Donna@epa.gov>
Sent: Friday, December 20, 2019 10:41 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

I took a run at developing a document that I think is the right level of detail and tone for briefing the AA.

Mike/Dan,
Please advise if this is the right level of detail to brief up.

Marion/Debra,
If Mike/Dan concur this works, I suspect it needs a little more work and a few tweaks, but can you take the lead in finalizing?

Donna

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Thursday, December 19, 2019 1:27 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Davis, Donna <Davis.Donna@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: FW: Aldicarb Memo
Importance: High

Mike,

Ex. 5 Deliberative Process (DP)

Regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
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Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, December 19, 2019 12:51 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb memo - corrected

Marion,

I made the corrections to the memo that you dropped off and we discussed in this version.

Thanks,

Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Aldicarb Proposed Use on Citrus Issue Paper

January 14, 2020

Issue

AgLogic Chemical LLC (AgLogic) submitted an application for registration of new uses of aldicarb on oranges and grapefruit in Florida and Texas to control Asian citrus psyllid responsible for transmission of citrus greening. OPP met with the registrant to discuss the specific risk concerns with the proposed new uses for this active ingredient. Understanding the challenges, the registrant elected to make a submission on April 9, 2019. The PRIA due date for this action is July 15, 2020. Having completed review of the submission,

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

OPP

would like to alert the interested parties of our findings as soon as possible. There has been congressional interest on the progress and pending outcome of this application.

Regulatory History

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity, and to protect ground water.
- Aldicarb products are currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. There are no registered residential uses of aldicarb.
- In 2010, Bayer (the registrant at that time) voluntarily agreed to cancel the domestic aldicarb uses on citrus (and potatoes), due to the findings by EPA that the registered uses posed an unacceptable dietary risk, especially to infants and young children. However, the existing tolerances for citrus have been maintained to allow for treated imports. Further, the registrant adopted risk mitigation measures for the remaining uses to protect groundwater resources.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.

Ex. 5 Deliberative Process (DP)

Current Submission

Ex. 5 Deliberative Process (DP)

- **Ex. 5 Deliberative Process (DP)**

Benefits

- Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives. **Ex. 5 Deliberative Process (DP)**

- **Ex. 5 Deliberative Process (DP)**

- Use of aldicarb tends to produce higher yields.

- **Ex. 5 Deliberative Process (DP)**

EPA's Current Evaluation of the Requested Use on Citrus in Florida and Texas

- OPP technical experts reviewed the white papers and analyses submitted by the registrant. The white papers suggested **Ex. 5 Deliberative Process (DP)**

- **Ex. 5 Deliberative Process (DP)**

- OPP conducted a revised exposure assessment, which included the proposed domestic uses on oranges and grapefruit.

- **Ex. 5 Deliberative Process (DP)**
 -

- **Ex. 5 Deliberative Process (DP)**

Proposed Next Steps

- **Ex. 5 Deliberative Process (DP)**

Aldicarb Proposed Use on Citrus Issue Paper
DRAFT December 20, 2019

Commented

Update

Issue

AgLogic Chemical LLC (AgLogic) submitted an application for registration of new uses of aldicarb on oranges and grapefruit in Florida and Texas to control Asian citrus psyllid responsible for transmission of citrus greening. OPP met with the registrant to discuss the specific risk concerns/challenges with the proposed new uses for this active ingredient.

Understanding the challenges, the registrant elected to make a submission on April 9, 2019. The PRIA due date for this action is July 15, 2020. Having completed review of the submission:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

OPP would like to alert the interested parties of our findings as soon as possible. There has been congressional interest on the progress and pending outcome of this application.

Regulatory History

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity, and to protect ground water.
- Aldicarb products are currently registered for use in various agricultural areas on cotton, dry beans (CO, OR, WA, ID, MT), peanuts, soybeans (GA, NC, SC, VA), sugar beets (CA, CO, ID, MT, NE, OR, WA, WY), and sweet potatoes (LA, MS). There are no registered residential uses of aldicarb.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

In 2010, Bayer (the registrant at that time) voluntarily agreed to cancel the domestic aldicarb uses on citrus (and potatoes), due to the findings by EPA that the registered uses posed an unacceptable dietary risk, especially to infants and young children. However, the existing tolerances for citrus have been maintained to allow for treated imports.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Further, the registrant adopted risk mitigation measures for the remaining uses to protect groundwater resources.

- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Current Submission

Ex. 5 Deliberative Process (DP)

Benefits

- Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives.
- Use of aldicarb tends to produce higher yields.

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

Alternatives

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Ex. 5 Deliberative Process (DP)

EPA's Current Evaluation of the Requested Use on Citrus in Florida and Texas

- OPP technical experts reviewed the white papers and analyses submitted by the registrant. The white papers suggested

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Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Proposed Next Steps

Ex. 5 Deliberative Process (DP)

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 1/15/2020 4:30:15 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb - Revisions (with and with out comments)

No worries. I don't mind. I'm still in a meeting but I should be out by 12 pm.

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Wednesday, January 15, 2020 11:29 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Revisions (with and with out comments)

Debra –

Ex. 5 Deliberative Process (DP)

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
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Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Wednesday, January 15, 2020 11:27 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Revisions (with and with out comments)

Sorry, I haven't yet.

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Wednesday, January 15, 2020 11:20 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Revisions (with and with out comments)

Okay. . . thanks! I'll go ahead and finalize it, unless you've already done so.

MJJ

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
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Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Wednesday, January 15, 2020 11:01 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Revisions (with and with out comments)

Nothing further from me.

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Wednesday, January 15, 2020 10:45 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Revisions (with and with out comments)
Importance: High

Debra,

Ex. 5 Deliberative Process (DP)

Marion J.

Marion J. Johnson, Jr.
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Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Wednesday, January 15, 2020 7:49 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Revisions (with and with out comments)

Hi Marion,

Ex. 5 Deliberative Process (DP)

Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Tuesday, January 14, 2020 4:47 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Revisions (with and with out comments)

Thanks, Debra! I just wanted to get back to Mike with a status prior to his inquiring. Fit it [your review] in wherever you can. . . .

MJJ

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, January 14, 2020 4:38 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Revisions (with and with out comments)

Will read it tonight and have any other input ready for tomorrow morning as you indicated to Mike G. Thanks! Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Tuesday, January 14, 2020 4:28 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Revisions (with and with out comments)

Debra,

These are my final comments, in light of Mike's latest round of questions. Let me know your thoughts, but I think we should move to finalize it. Many thanks!

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs

Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, January 14, 2020 9:56 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb - Revisions (with and with out comments)

Hi Marion,

Here is the latest version with and without comments. Let me know what you think.
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 1/15/2020 12:49:27 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb - Revisions (with and with out comments)
Attachments: Aldicarb Citrus New Use Summary Paperm 1.14.20 dnrnj Comments (002).docx

Hi Marion,

Ex. 5 Deliberative Process (DP)

Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Tuesday, January 14, 2020 4:47 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Revisions (with and with out comments)

Thanks, Debra! I just wanted to get back to Mike with a status prior to his inquiring. Fit it [your review] in wherever you can. . . .

MJJ

Marion J. Johnson, Jr.
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Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, January 14, 2020 4:38 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Revisions (with and with out comments)

Will read it tonight and have any other input ready for tomorrow morning as you indicated to Mike G. Thanks! Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Tuesday, January 14, 2020 4:28 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Aldicarb - Revisions (with and with out comments)

Debra,

These are my final comments, in light of Mike's latest round of questions. Let me know your thoughts, but I think we should move to finalize it. Many thanks!

Marion J.

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Chief, Invertebrate-Vertebrate Branch 2
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Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, January 14, 2020 9:56 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb - Revisions (with and with out comments)

Hi Marion,

Here is the latest version with and without comments. Let me know what you think.

Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Aldicarb Proposed Use on Citrus Issue Paper
January 14, 2020

Issue

AgLogic Chemical LLC (AgLogic) submitted an application for registration of new uses of aldicarb on oranges and grapefruit in Florida and Texas to control Asian citrus psyllid responsible for transmission of citrus greening. OPP met with the registrant to discuss the specific risk concerns with the proposed new uses for this active ingredient. Understanding the challenges, the registrant elected to make a submission on April 9, 2019. The PRIA due date for

Ex. 5 Deliberative Process (DP)

would like to alert the interested parties of our findings as soon as possible. There has been congressional interest on the progress and pending outcome of this application.

Regulatory History

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity, and to protect ground water.
- Aldicarb products are currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. There are no registered residential uses of aldicarb.
- In 2010, Bayer (the registrant at that time) voluntarily agreed to cancel the domestic aldicarb uses on citrus (and potatoes), due to the findings by EPA that the registered uses posed an unacceptable dietary risk, especially to infants and young children. However, the existing tolerances for citrus have been maintained to allow for treated imports. Further, the registrant adopted risk mitigation measures for the remaining uses to protect groundwater resources.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.
 - The EPA risk assessment for the 2017 ID depicted risk estimates for dietary (food only) exposure below the level of concern, which included citrus exposure from imported commodities only.
 - Drinking water risks were mitigated by appropriate well setbacks, based upon such factors such as location and soil type, and with consideration that in-furrow applications were at a depth of the one inch or greater. This analysis was inclusive for citrus in FL, even though aldicarb's domestic use on citrus had been voluntarily cancelled.

Current Submission

- To support the registration of aldicarb on citrus in Florida and Texas, AgLogic did not submit new data, but instead conducted their own dietary exposure and drinking water exposure assessments. The company asserts that these analyses demonstrate that there are no risks of concern for the proposed new use on citrus.

- Further, the company contends that, since there are already tolerances established for the use on citrus, the agency does not need to make a safety finding to support these new uses.

Benefits

- Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives.
- Use of aldicarb tends to produce higher yields.

Ex. 5 Deliberative Process (DP)

EPA's Current Evaluation of the Requested Use on Citrus in Florida and Texas

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Ex. 5 Deliberative Process (DP)

Proposed Next Steps

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Confidential/Internal/Deliberative DRAFT

Ex. 5 Deliberative Process (DP)

[PAGE * MERGEFORMAT]

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 1/14/2020 9:32:05 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]; Davis, Donna [Davis.Donna@epa.gov]
CC: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]
Subject: RE: Aldicarb Memo

Mike –

We have addressed your comments and will be forwarding that inclusive document by first thing tomorrow morning. I just wanted you to know that it's been worked on and completed, but I want to ensure that the team agrees with the changes provided, as the last team step in the process.

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
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(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Sunday, January 12, 2020 4:23 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

Thanks everyone – attached are some edits/comments. Feel free to change any edits that I made that are not correct. Let me know if you have questions.

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157
Room S7623

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Thursday, January 09, 2020 5:16 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo
Importance: High

Mike, et.al.:

Please disregard the first document below, as I failed to “delete all comments”. I’m attaching the final edited document, as required. Many thanks!

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
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Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Johnson, Marion
Sent: Thursday, January 9, 2020 12:14 PM
To: Goodis, Michael <Goodis.Michael@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

Mike,

Attached is the most updated aldicarb “one pager” which incorporates responses to your questions/comments. The second document contains your original comments and has been provided for comparison purposes only, as track changes were becoming too distracting. Thus, we think that we’ve addressed your thoughts, while still keeping the document tailored and structured to the AA’s needs. However, let us know, if you have further questions.

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
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From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Monday, December 30, 2019 2:57 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

Ex. 5 Deliberative Process (DP)

Let me know if you have any questions.

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

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From: Johnson, Marion <Johnson.Marion@epa.gov>
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To: Davis, Donna <Davis.Donna@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
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Subject: RE: Aldicarb Memo

Donna, et. al.:

Thanks for pulling this together.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Otherwise, I'm fine

with this version but let me know if you have additional thoughts.

Best regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
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Visit: <http://www.epa.gov/pesticides>

From: Davis, Donna <Davis.Donna@epa.gov>
Sent: Friday, December 20, 2019 10:41 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Aldicarb Memo

I took a run at developing a document that I think is the right level of detail and tone for briefing the AA.

Mike/Dan,

Please advise if this is the right level of detail to brief up.

Marion/Debra,

If Mike/Dan concur this works, I suspect it needs a little more work and a few tweaks, but can you take the lead in finalizing?

Donna

From: Johnson, Marion <Johnson.Marion@epa.gov>

Sent: Thursday, December 19, 2019 1:27 PM

To: Goodis, Michael <Goodis.Michael@epa.gov>

Cc: Davis, Donna <Davis.Donna@epa.gov>; Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Rate, Debra <Rate.Debra@epa.gov>

Subject: FW: Aldicarb Memo

Importance: High

Mike,

Ex. 5 Deliberative Process (DP)

Regards,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
(703) 305-6788 (tel)
(703) 308-0029 (fax)
Johnson.marion@epa.gov
Visit: <http://www.epa.gov/pesticides>

From: Rate, Debra <Rate.Debra@epa.gov>

Sent: Thursday, December 19, 2019 12:51 PM

To: Johnson, Marion <Johnson.Marion@epa.gov>

Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>

Subject: Aldicarb memo - corrected

Marion,

I made the corrections to the memo that you dropped off and we discussed in this version.
Thanks,

Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 1/14/2020 9:27:44 PM
To: Rate, Debra [Rate.Debra@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Aldicarb - Revisions (with and with out comments)
Attachments: Aldicarb Citrus New Use Summary Paperm 1.14.20 dnrnj No Comments (002).docx

Debra,

These are my final comments, in light of Mike's latest round of questions. Let me know your thoughts, but I think we should move to finalize it. Many thanks!

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
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Registration Division
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Johnson.marion@epa.gov
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From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Tuesday, January 14, 2020 9:56 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Aldicarb - Revisions (with and with out comments)

Hi Marion,

Here is the latest version with and without comments. Let me know what you think.
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Aldicarb Proposed Use on Citrus Issue Paper

~~DRAFT~~ January 14, 2020

Issue

AgLogic Chemical LLC (AgLogic) submitted an application for registration of new uses of aldicarb on oranges and grapefruit in Florida and Texas to control Asian citrus psyllid responsible for transmission of citrus greening. OPP met with the registrant to discuss the specific risk concerns with the proposed new uses for this active ingredient. Understanding the challenges, the registrant elected to make a submission on April 9, 2019. The PRIA due date for

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Regulatory History

- Aldicarb is an N-methyl carbamate (NMC) insecticide registered for use to control certain insects, mites, and nematodes.
- Aldicarb products are restricted use pesticides (RUPs) due to acute oral, dermal and inhalation toxicity, and to protect ground water.
- Aldicarb products are currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. There are no registered residential uses of aldicarb.
- In 2010, Bayer (the registrant at that time) voluntarily agreed to cancel the domestic aldicarb uses on citrus (and potatoes), due to the findings by EPA that the registered uses posed an unacceptable dietary risk, especially to infants and young children. However, the existing tolerances for citrus have been maintained to allow for treated imports. Further, the registrant adopted risk mitigation measures for the remaining uses to protect groundwater resources.
- The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer.
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.
 - The EPA risk assessment for the 2017 ID depicted risk estimates for dietary (food only) exposure below the level of concern, which included citrus exposure from imported commodities only.
 - Drinking water risks were mitigated by appropriate well setbacks, based upon such factors such as location and soil type, and with consideration that considering in-furrow applications were at a depth of the one inch or greater. This analysis was inclusive for citrus in FL, even though aldicarb's domestic use on citrus had been voluntarily cancelled.

Current Submission

- To support the registration of aldicarb on citrus in Florida and Texas, AgLogic did not submit new data, but instead conducted their own dietary exposure and drinking water exposure assessments. The company asserts that these analyses demonstrate that there are no risks of concern for the proposed new use on citrus.

- Further, the company contends that, since there are already tolerances established for the use on citrus, the agency does not need to make a safety finding to support these new uses.

Benefits

- Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives.
- Use of aldicarb tends to produce higher yields.
- Based on the broad-spectrum nature of this carbamate, it is likely to control the Asian citrus psyllid; however, aldicarb's role in controlling citrus greening and whether it is more efficacious than the 13 alternatives (including the recent registration of sulfoxaflor on citrus) are unknown.

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EPA's Current Evaluation of the Requested Use on Citrus in Florida and Texas

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Ex. 5 Deliberative Process (DP)

